

2007 Annual Report



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Chelsea Therapeutics International, Ltd.



CHELSEA
THERAPEUTICS



CHELSEA THERAPEUTICS

Chelsea Therapeutics is a biopharmaceutical company developing branded prescription products for the treatment of a variety of human diseases. Chelsea's most advanced clinical compound, Droxidopa, is being developed for the treatment of neurogenic orthostatic hypotension, an indication for which it is approved and marketed in Japan. In addition to expanding the potential applications for Droxidopa, Chelsea is also developing a library of metabolically inert antifolate compounds and a portfolio of DHODH inhibiting therapeutics targeting blockbuster immune-mediated inflammatory disorders and transplantation indications.

Strong and Balanced Pipeline

Droxidopa, approved and marketed in Japan since 1989, is an orally active synthetic precursor of norepinephrine in Phase III development in the U.S./EU for the treatment of orthostatic hypotension. By replenishing depleted norepinephrine via the endogenous enzymatic pathway, Droxidopa allows for re-uptake of norepinephrine into peripheral nervous system neurons – stimulating receptors for vasoconstriction and providing physiological improvement in symptomatic neurogenic orthostatic hypotension.

Chelsea is also conducting Phase II trials of Droxidopa in other therapeutic indications for which it either has previously shown or is believed to provide potential therapeutic benefit including Intradialytic Hypotension and Fibromyalgia.

CH-1504 is a Phase II, orally available and metabolically inert antifolate that has potent anti-inflammatory and anti-tumor properties, potentially inhibiting several key enzymes that are required for cell proliferation.

Combining lower risk market opportunities and potential blockbuster indications

Droxidopa:

- Proven Safety and Efficacy
 - Marketed Ex US (Japan) since 1989
 - Million+ years of patient data
- Attractive Market Opportunity in Proven Indications
 - \$400m+ US market for neurogenic orthostatic hypotension (NOH)
 - \$85m+ US market for intradialytic hypotension
- Significant Upside Potential in Additional Indications

Fibromyalgia	Chronic Fatigue
Freezing	Gait Pain

Metabolically Inert Antifolates:

- Engineered for improved safety and increased tolerability
- Potential first line and combination treatment for rheumatoid arthritis
- Pilot RA clinical study demonstrated improved efficacy and superior safety & tolerability vs. methotrexate
- Additional high potential global markets:

Psoriasis	Cancer
Other immunological disorders	

Preclinical and pilot clinical data suggest increased potency versus Methotrexate (MTX), currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases. Preclinical data further indicates that CH-1504 inhibits the growth of human tumor cells in culture and has anti-tumor activity in animal xenograft studies. Chelsea has additional antifolate compounds at earlier stages of development.

The **I-3D portfolio** consists of an extensive library of orally active therapeutic compounds targeting autoimmune diseases and transplant rejection. Compounds from this portfolio have demonstrated potent inhibition of dihydroorotate dehydrogenase (DHODH) activity while maintaining PK and safety properties superior to the marketed DHODH inhibitor during preclinical testing.

Key Potential Value Drivers

- Pivotal Phase III Clinical Trials of Droxidopa for the treatment of Neurogenic Orthostatic Hypotension
- Proof-of-Concept Phase II Clinical Trials of CH-1504 for the Treatment of Rheumatoid Arthritis
- Dose Finding Phase II Clinical Trial of Droxidopa in Intradialytic Hypotension
- Exploratory Phase II Clinical Trial of Droxidopa in Fibromyalgia
- Extramural Programs in Additional Areas of Interest
- Development of Once-A-Day Formulation of Droxidopa and associated strengthening of IP

Letter to Stockholders

Fellow Stockholders,

We have entered a defining year at Chelsea. This is a year in which we not only have a pivotal phase III program and two phase II trials already underway but also two additional trials planned for the year ahead. The outcome of each has the potential to dramatically transform Chelsea and drive significant value creation for our stockholders. The results of this heightened clinical activity should provide the data necessary to file for our first marketing approval, for neurogenic orthostatic hypotension in 2009; provide definitive proof-of-concept in two large indications, rheumatoid arthritis and fibromyalgia; and expand the potential market opportunity for Droxidopa into intradialytic hypotension.

As we look ahead to our execution in these programs, we are committed to not only achieving these milestones but doing so while taking all actionable steps to help ensure the positive clinical outcome we believe each program can deliver. We would not, however, be in such a strong position to execute against this goal in 2008 were it not for the significant preparations undertaken in 2007.

Comprehensive Phase III Program in Neurogenic Orthostatic Hypotension

One of the considerable advantages to our Droxidopa program is the knowledge that Droxidopa is a safe and effective treatment for neurogenic orthostatic hypotension (NOH), as demonstrated by the extensive clinical testing and subsequent long-term use by tens of thousands of patients in Japan. From the beginning, the greatest risk associated with our development of Droxidopa has been a regulatory risk, and in that regard we made substantial progress further de-risking the program in 2007.

We started the year by securing orphan designation for Droxidopa in NOH to provide the critical, initial marketing exclusivity in our lead indication. In addition to securing orphan designation, we also met with the FDA early in the year to determine the clinical requirements for regulatory approval and were pleased by the agency's acceptance of the comprehensive data generated by Dainippon Sumitomo and their rapid buy-in to move the compound directly into Phase III testing.

The most significant discussions with the FDA regarding Droxidopa came later and centered on the review of our Phase III protocol. We believe the acceptance of our enrichment design, combined with the small size and relatively short duration of both trials are positive developments in the approval process. The most tangible evidence of this and greatest de-risking event for this program is the Special Protocol Assessment we received for study 301.

In an era in which so many companies are facing significant challenges from the FDA, we are very encouraged by not only the tone of each of our meetings with the agency to date, but also the successful outcome of each of these interactions so far.

Successful Reformulation of CH-1504

One of the most significant developments for Chelsea in 2007 was the validation of our successful reformulation of CH-1504, the lead candidate in our portfolio of metabolically inert antifolates. In the second quarter of 2007, we initiated a bioequivalence study of CH-1504 that allowed us to evaluate the relative bioavailability of the new formulation and fulfill the regulatory requirements for the commencement of Phase II testing.

The results of this evaluation exceeded our expectations with a greater than 10-fold improvement in relative bioavailability. With increased bioavailability, we believe we dramatically decrease the potential for variability in plasma levels and thus increase the likelihood of a more predictable clinical response using substantially lower doses of CH-1504 in our ongoing Phase II head-to-head comparison against methotrexate.

Expanded Pipeline Potential

In concert with our efforts to advance both Droxidopa and CH-1504 in their respective lead indications, in 2007 we initiated several programs that will significantly expand the potential uses for our pipeline. Specifically, we announced our intent to begin development in intradialytic hypotension (IDH) as well as our interest in evaluating the efficacy of Droxidopa in fibromyalgia. Both of these indications are now active programs and each offers compelling upside to the value of the compound.

As IDH is another approved indication in Japan, it offers a second opportunity for us to leverage the existing Japanese data to expand the potential market for Droxidopa here in the United States. It is a market that is predicted to grow significantly as the number of patients undergoing dialysis continues to increase and, with no approved therapeutic in the indication, there remains a compelling unmet need for a safe and effective therapeutic option.

The next indication we are exploring with Droxidopa is Fibromyalgia. While the indication is not one that is approved in Japan, there is sufficient evidence from prior clinical investigation – specifically in pain – to suggest that Droxidopa could be a well tolerated and effective treatment option in this potential blockbuster indication. In addition to providing a significant new market opportunity for Droxidopa, work in this indication could yield enhanced IP protection through the use of combination therapy.

Similar to our work with Droxidopa, we are taking a comprehensive approach to the development of our full portfolio of antifolate drug candidates. Having progressed into Phase II evaluation of CH-1504 in rheumatoid arthritis, we began more aggressive development of CH-4051, our fast follower to CH-1504. Preliminary results from our ongoing IND enabling toxicology work have been compelling and we look forward to advancing CH-4051 into Phase I trials later this year. As the applications for successful antifolate compounds are broad, we also plan to begin preclinical work on several additional compounds in this portfolio.

A Productive and Rewarding 2008

As a result of our efforts in 2007, we believe we are well positioned to execute on five meaningful clinical trials in a broad range of indications, each offering an opportunity to increase the value of our portfolio dramatically. There remains much work to be done, but we are looking forward to not only taking significant steps toward commercialization of our first product but also significantly adding to the breadth of data and therapeutic applications of our pipeline in 2008.

On behalf of everyone at Chelsea, I thank you for your continued support and look forward to updating you regularly on our progress.



Dr. Simon Pedder, PhD
Chief Executive Officer

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

- ☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2007, OR
- ☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM _____ TO _____
Commission file number 000-51462

CHELSEA THERAPEUTICS INTERNATIONAL, LTD.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

20-3174202
(I.R.S. Employer Identification No.)

13950 Ballantyne Corporate Place, Suite 325, Charlotte, North Carolina 28277
(Address of principal executive offices, including zip code)

(704) 341-1516
(Registrant's telephone number, including area code)

Title of each class
Common Stock, \$0.0001 Par Value

Name of each exchange on which registered
Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, \$0.0001 Par Value

Indicate by check mark if the Registrant is a well-known seasoned issuer (as defined in Rule 405 of the Securities Act).
Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐
Non-accelerated filer ☐

Accelerated filer ☒
Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the Registrant, based on the closing price of the Registrant's common stock on June 29, 2007 (\$6.69 per share) was \$94,943,477. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At March 7, 2008, 29,962,168 shares of the Registrant's common stock, \$.0001 par value per share, were outstanding.

Documents Incorporated By Reference

Portions of the Registrant's definitive Proxy Statement to be filed for its 2008 Annual Meeting of Stockholders currently scheduled to be held June 26, 2008 are incorporated by reference into Part III of this report.

ANNUAL REPORT ON FORM 10-K

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PART I

Except for the historical information contained herein, the matters set forth in this Report include forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties are detailed throughout the report and will be further discussed from time to time in our periodic reports filed with the Commission. The forward-looking statements included in this Report speak only as of the date hereof.

ITEM 1. DESCRIPTION OF BUSINESS.

Overview

We are a development stage pharmaceutical company that seeks to acquire and develop innovative products for the treatment of a variety of human diseases. Our strategy is to develop technologies that address important unmet medical needs or offer improved, cost-effective alternatives to current methods of treatment. Specifically, we concentrate our efforts on acquiring and developing technologies for the treatment of rheumatoid arthritis, autonomic nervous system conditions, psoriasis, inflammatory bowel disease, cancer and other disorders or technologies that will compliment this core focus.

Product Pipeline Summary

Currently, we are currently developing two platform technologies that each consist of a portfolio of molecules for the treatment of various autoimmune/inflammatory diseases. The first and most advanced platform is a portfolio of metabolically inert antifolate molecules engineered to have potent anti-inflammatory and anti-tumor activity to treat a range of immunological disorders, including our lead antifolate product candidate CH-1504. CH-1504 is an orally available molecule with potent anti-inflammatory, autoimmune and anti-tumor properties that potentially inhibits several key enzymes that are required for cell proliferation. Preclinical and clinical data to date suggests superior safety and tolerability, as well as increased potency versus methotrexate (MTX), currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases. Diseases that may potentially benefit from the compound include rheumatoid arthritis, psoriasis, inflammatory bowel disease, psoriatic arthritis and several different kinds of cancer. In January 2008, we initiated a Phase II head-to-head clinical trial in rheumatoid arthritis to compare the efficacy and tolerability of CH-1504 against methotrexate. Complimenting our antifolate program is the second platform consisting of a portfolio of dihydroorotate dehydrogenase, or DHODH, inhibiting compounds known as the I-3D portfolio being developed in a strategic partnership with Active Biotech AB, from whom we obtained North and South American commercial rights. Current pre-clinical animal data for this portfolio of compounds have shown potential applications in autoimmune diseases and transplantation.

In addition to our autoimmune pipeline, we are developing droxidopa, an orally active synthetic precursor of norepinephrine, for the treatment of neurogenic orthostatic hypotension (NOH). Currently approved and marketed in Japan for the treatment of symptomatic orthostatic hypotension, freezing gait in Parkinson's disease and intra-dialytic hypotension, droxidopa has accumulated over 15 years of proven safety and efficacy, historically generating annual revenues of approximately \$50 million in Japan. In 2007, the US Food & Drug Administration (FDA) granted orphan drug designation to droxidopa in the treatment of symptomatic neurogenic orthostatic hypotension associated with primary autonomic failure (Parkinson's disease, Pure Autonomic Failure and Multiple Systems Atrophy). The European Commission granted orphan medical product designation to droxidopa in patients with Pure Autonomic Failure (PAF) and patients with Multiple Systems Atrophy (MSA). In February 2008, we began patient dosing in a double-blind pivotal Phase III trial. The Phase III trial is designed to compare droxidopa to placebo at multiple sites in the United States and Europe and is intended to assess the safety and efficacy of droxidopa in patients suffering from symptomatic NOH associated with Parkinson's disease, PAF and MSA with the primary efficacy endpoint being defined as the relative symptomatic change, as

measured by the mean score of Item 1 (dizziness or lightheadedness) of the Orthostatic Hypotension Symptom Assessment, fourteen (14) days following randomization either to continued therapy with droxidopa or to placebo.

We also have an active in-licensing and acquisition program designed to identify and acquire additional drug candidates. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

Our Strategy

Our mission is to create long-term stockholder value by acquiring, developing and commercializing innovative products for the treatment of a variety of human diseases that address important unmet medical needs or offer improved, cost-effective alternatives to current methods of treatment. Since inception in 2002, we have focused primarily on organizing and staffing our company, negotiating in-licensing agreements with our partners, acquiring, developing and securing our proprietary technology, synthesizing and manufacturing of investigational compounds, participating in regulatory discussions with the FDA, the European Medicines Agency, or the EMEA, and other regulatory agencies, undertaking pre-clinical and clinical trials of our product candidates and raising capital. We are a development stage company and have generated no revenues since inception. We do not anticipate generating any product revenue until approvals are successfully obtained from the FDA or equivalent foreign regulatory bodies to begin selling pharmaceutical/biotech candidates.

We expect the progress of our development programs to be a primary factor affecting our expenses, losses and cash position in the future. In early 2008, we initiated, or plan to initiate, four separate Phase II or Phase III clinical programs as follows:

- Phase III program for droxidopa in neurogenic orthostatic hypotension, requiring approximately 236 patients;
- Phase II program for CH-1504 in rheumatoid arthritis, requiring approximately 200 patients;
- Phase II program for droxidopa in hypotension associated with dialysis, requiring approximately 75 patients; and
- Phase II program for droxidopa in fibromyalgia, requiring approximately 90 patients.

We also continue to discuss our antifolate program with large pharmaceutical companies to gauge their interest in licensing this library of compounds, however, we do not anticipate reaching an agreement concerning these compounds until, at the earliest, the conclusion of our Phase II trial for CH-1504 in rheumatoid arthritis, if at all. We believe a partner may be able to manage Phase III trials and global commercialization more effectively and with less risk than we could and accordingly, our current strategy is to pursue such a partnership. Any such partnership must provide significant value to us and our stockholders, while maximizing the opportunities for these compounds in global markets. We believe that the completion of a successful Phase II trial is likely to enhance the terms under which such a partnership can be reached and accordingly, we anticipate that post Phase II might be the most beneficial time to finalize such an arrangement. We will consider such an arrangement sooner if it is likely to strengthen our financial position, but only if the perceived discount is modest enough to justify these benefits. Similarly, we do not anticipate a licensing arrangement for droxidopa in Europe until we have a better understanding of the efficacy of this compound in certain indications such as fibromyalgia, which we currently anticipate would be 2009, at the earliest.

We have retained a management team with leading core competencies and expertise in numerous fields, including manufacturing, research, clinical, regulatory and business development. Our management and advisors are comprised of experienced pharmaceutical and biotechnology industry veterans and respected experts. We are led by our Chief Executive Officer, Dr. Simon Pedder, formerly Vice President, Pharmaceutical Business,

Oncology at Hoffmann-La Roche Inc., who has over 16 years of senior pharmaceutical management experience, including drug development and business experience. During his time at Roche, Dr. Pedder was responsible for a number of global development programs, successful registrations and product launches.

Plan of Operation

Our plan of operation is to continue implementing our business strategy, especially the clinical development of our current drug candidates including droxidopa and our portfolio of antifolates. We also continue to explore the feasibility of other licensed or newly developed compounds and to expand our drug candidate portfolio by acquiring additional drug technologies for development. We expect our principal expenditures during the next 18 months to include:

- operating expenses, including marketing, general and administrative and business development expenses; and
- product development expenses, including the costs incurred with respect to our clinical trials for droxidopa, antifolates and compounds from the I-3D portfolio and/or additional compounds that we may license.

As part of our planned expansion, we anticipate hiring additional scientific, marketing, and administrative staff. In addition, we intend to continue using clinical research organizations and third parties to perform our clinical studies and manufacturing.

Corporate History

Our operating company was incorporated in Delaware in April 2002 under the name Aspen Therapeutics, Inc., and changed its name to Chelsea Therapeutics, Inc. in July 2004. On February 11, 2005, Chelsea Therapeutics, Inc. completed a merger with Ivory Capital Corporation, a publicly traded Colorado corporation formed in May 1988. At the time of the transaction, Ivory Capital had only nominal assets and no operating activities. In connection with this merger transaction, a wholly owned subsidiary of Ivory Capital Corporation merged with and into Chelsea Therapeutics, Inc., with Chelsea Therapeutics, Inc. remaining as the surviving corporation and a wholly owned subsidiary of Ivory Capital Corporation. In connection with the merger, the former stockholders of Chelsea Therapeutics, Inc. received 96.75% percent of our outstanding equity on a fully diluted basis. Pursuant to the terms of the merger, the sole officer and director of Ivory Capital Corporation prior to the merger was replaced with the officers and directors of Chelsea Therapeutics, Inc.

On June 17, 2005, Ivory Capital Corporation formed a wholly owned subsidiary in Delaware named Chelsea Therapeutics International, Ltd. for the purposes of reincorporating in Delaware. On July 28, 2005, Ivory Capital Corporation merged with Chelsea Therapeutics International, Ltd., with Chelsea Therapeutics International, Ltd. as the surviving corporation. As a result, Chelsea Therapeutics International, Ltd. is the public reporting company and is the 100% owner of Chelsea Therapeutics, Inc., its operating subsidiary.

Except where the context provides otherwise, references to "we," "us," "our" and similar terms mean Chelsea Therapeutics International, Ltd., Ivory Capital Corporation and Chelsea Therapeutics, Inc. When we refer to business and financial information relating to periods prior to December 31, 2004, we are referring to the business and financial information of Chelsea Therapeutics, Inc. unless the context requires otherwise. When we refer to business and financial information for periods between January 1, 2005 and July 28, 2005, we are referring to the business and financial information of Ivory Capital Corporation.

Products Under Development

DROXIDOPA

Overview

Orthostatic hypotension is a sudden, decrease in blood pressure when a person assumes a standing position and is characterized by lightheadedness, dizziness, blurred vision and syncope. There are multiple known causes for orthostatic hypotension including those that are considered cardiovascular, endocrine or neurological (or neurogenic) in nature.

Neurogenic orthostatic hypotension results from a deficient release and/or activity of norepinephrine, a neurotransmitter used by autonomic nerves to send signals to the blood vessels and the heart.

We estimate that nearly 300,000 patients suffer from chronic, symptomatic NOH in the United States and the European Union. This condition is commonly associated with Parkinson's disease, pure autonomic failure and multiple system atrophy, a name that encompasses disorders previously known as striatonigral degeneration, olivoponto-cerebellar atrophy and the Shy-Drager syndrome.

Product Description

Droxidopa is an orally active synthetic precursor of norepinephrine currently approved and marketed by Dainippon Sumitomo Pharma Co., Ltd., or DSP, in Japan for the treatment of orthostatic hypotension. By producing and replenishing depleted norepinephrine via endogenous enzymatic pathway, droxidopa is believed to allow for the re-uptake of norepinephrine into peripheral nervous system neurons and/or stimulating receptors for vasoconstriction and providing physiological improvement in symptomatic NOH patients.

Originally approved in 1989 for the treatment of frozen gait or dizziness associated with Parkinson's disease and for the treatment of orthostatic hypotension, syncope or dizziness associated with Shy-Drager syndrome and Familial Amyloidotic Polyneuropathy, DSP expanded its Japanese marketing approval in 2000 to include prevention of vertigo, dizziness and weakness associated with hypotension in patients with end stage renal disease undergoing hemodialysis.

Clinical Development

In January 2007, the FDA granted orphan drug status for droxidopa for the treatment of symptomatic NOH in patients with primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine- β -hydroxylase deficiency, or nondiabetic autonomic neuropathy. In the United States, orphan drug status provides seven (7) years of marketing exclusivity and may impact FDA requirements for clinical trials, potentially reducing the time and expense required for such trials. In August 2007, the European Commission granted two orphan medicinal product designations for droxidopa for the treatment of orthostatic hypotension in patients with PAF and MSA. Although we can expect 10 years of data exclusivity for droxidopa upon approval in Europe as a new chemical entity, orphan drug status could impact requirements for clinical trials in Europe, thereby reducing the time and costs associated with our development of droxidopa for this market.

In securing development rights from DSP, we obtained exclusive access to a substantial body of clinical safety and efficacy data related to droxidopa's twenty-year combined clinical and commercial development by DSP. We believe this data to be applicable to both the United States and European Union regulatory approval processes. This data is expected to reduce the required clinical testing for United States and European Union marketing approval and expedite critical path to commercialization. We have initiated a global Phase III trial of droxidopa in February 2008 that, in combination with data secured from DSP, is expected to support applications for marketing approval in both the United States and the European Union, although we believe at least one additional trial may be required for approval in the European Union. We cannot predict with certainty the timing of our clinical trials. However, we currently estimate market launch no sooner than 2010.

Additional Potential Indications for Droxidopa

As we proceed to develop droxidopa for the treatment of symptomatic NOH, an indication for which we believe there exists a strong body of available clinical data and an immediate commercial opportunity, we will also evaluate other therapeutic indications for which we believe droxidopa either has shown or may provide clinical benefit.

Intradialytic hypotension, or IDH, is the most common adverse event during routine hemodialysis. IDH is often defined as a decrease in systolic blood pressure by ≥ 20 mm Hg or a decrease in mean arterial pressure by 10 mm Hg. IDH has been reported in 15-25% of all hemodialysis patients, with elderly patients reporting an even higher incidence. Many adverse hemodialysis events, including headaches, lightheadedness, nausea, cramps, and seizures, are associated with IDH. These complications can routinely interrupt dialysis sessions, resulting in insufficient uremia toxin removal and necessitating repetition of the procedure. Interruptions due to IDH increase the costs of both the dialysis treatment sessions and the long-term care of less healthy hemodialysis patients. Pivotal clinical studies conducted by DSP have demonstrated the efficacy of droxidopa in the prevention of vertigo, dizziness and weakness associated with hypotension in hemodialysis patients. Subsequently, in 2000, after showing benefit in clinical trials, DSP received expanded marketing approval in Japan for this indication.

In December 2007, we initiated a double-blind, placebo controlled Phase II clinical trial for droxidopa in the treatment of IDH. Conducted at multiple sites within the United States, the dose response study will compare droxidopa to placebo and will measure the change in mean blood pressure and symptomatic improvement compared to baseline established at the beginning of the study.

Prior independent clinical studies and ongoing research suggest that defects in the autonomic nervous system (such as altered norepinephrine levels and activity) may play a role in either the underlying cause or exacerbation of the symptoms associated with multiple diseases commonly grouped as dysautonomias. These indications include: chronic pain, urinary stress incontinence, postural orthostatic tachycardia syndrome, neurocardiogenic syncope, fibromyalgia and chronic fatigue syndrome.

Fibromyalgia is a polysymptomatic syndrome of unknown etiology characterized by chronic, widespread musculoskeletal pain, multiple tender points and abnormal pain sensitivity. Norepinephrine is known to play a key role in pain attenuation and droxidopa has shown statistically significant dose-dependent analgesia in chronic pain in prior studies conducted by DSP.

Additionally, scientists and physicians have suggested a strong association and/or significant correlation of symptoms between low blood pressure (caused by either NOH or neurally mediated hypotension (NMH)) and dysautonomia associated diseases. Research has shown a significant association between NMH and two specific dysautonomias, fibromyalgia, and chronic fatigue syndrome. Unlike NOH, which is a problem with blood pressure regulation immediately after standing, NMH is characterized by a drop in blood pressure only after standing for longer periods of time. NMH occurs due to a miscommunication between the heart and brain resulting in a failure to maintain appropriate increases in heart rate after standing for prolonged periods. This is believed to be a problem related specifically to deficient nerve function in the left ventricle that prevents the heart rate from increasing when needed. Instead of increasing, the heart rate actually drops, preventing the necessary amount of blood from being circulated. This leads to NMH symptoms like dizziness and fainting, which is often referred to as orthostatic intolerance. Patients with fibromyalgia, chronic fatigue syndrome and other dysautonomias often have orthostatic intolerance as a major symptom of their disease syndrome. As norepinephrine naturally regulates both heart rate and vasoconstriction, droxidopa could be an appropriate alternative therapy (among others such as salt, Florinef® and Midodrine) to treat that specific symptom by enhancing the body's ability to naturally regulate these functions. Further studies will be needed to determine the contribution of either NMH or NOH to other major components of autonomic diseases such as pain, fatigue, weakness, and incontinence. Furthermore, randomized trials will be needed to indicate whether droxidopa improves the hypotension and whether this in turn shows benefit in additional symptomatology within these disease syndromes.

We intend to conduct Phase II proof of concept trials to investigate the benefits of droxidopa, if any, in treating both the orthostatic intolerance symptom and the additional symptoms that make up the various dysautonomia conditions. We are currently working with key opinion leaders in fibromyalgia and chronic fatigue syndrome concerning the timing and size of an initial trial that would be expected to start in the second quarter of 2008.

While doctors have used antidepressants and pain drugs for years, the FDA approved the first drug specifically for fibromyalgia in June 2007; Pfizer's Lyrica®, which was already used to treat epilepsy and neuropathic pain. Eli Lilly has also applied to the FDA to market its antidepressant Cymbalta®, a selective serotonin and norepinephrine reuptake inhibitor, to treat fibromyalgia and Cypress Biosciences, with their partner Forest Laboratories, is developing milnacipran for the treatment of fibromyalgia. Milnacipran is a norepinephrine serotonin reuptake inhibitor that increases the level of norepinephrine more than it does serotonin.

Droxidopa Competition

Midodrine (ProAmatine®)

Midodrine is currently the only FDA approved therapeutic for the treatment of orthostatic hypotension. Midodrine, originally developed by Roberts Pharmaceuticals (later acquired by Shire®) under the brand name ProAmatine®, is an alpha-agonist that works by stimulating alpha receptors, subsequently increasing vasculature tone and thereby producing an elevation in blood pressure. Given this direct mechanism of action, it is not surprising that supine hypertension is the most frequently occurring adverse event associated with its use. Midodrine's product label contains a black box warning and Midodrine does not specifically address neurogenic orthostatic hypotension.

Other than the increase in blood pressure caused by vasoconstriction, additional midodrine side effects include paresthesia, piloerection, dysuria, and pruritis. Annual sales (branded and generic) in the United States total approximately \$60 million, based on 2005 data. In addition to Shire's manufacturing of the ProAmatine brand, Mylan Pharmaceuticals, Eon Labs and Impax Laboratories are generic manufacturers of the compound.

Fludrocortisone (Florinef®)

Fludrocortisone is also widely used in the treatment of orthostatic hypotension although this specific indication has not been approved by the FDA. Fludrocortisone is a synthetic adrenocortical steroid possessing very potent mineralocorticoid properties and high glucocorticoid activity. Fludrocortisone, in small oral doses (0.1 mg.) produces marked sodium retention and increased urinary potassium excretion leading to enhanced plasma volume and a rise in blood pressure. Side effects include hypertension, water & sodium retention and K⁺ loss. Fludrocortisone is not FDA approved for NOH and the mechanism of action for fludrocortisone does not specifically address this indication.

Droxidopa Marketing

Our marketing plan for droxidopa includes the establishment of a marketing and sales organization in the United States. With regard to the European Union and other markets, we would expect to partner with or license droxidopa to companies with established infrastructure in those markets.

METABOLICALLY INERT ANTIFOLATES & CH-1504

Overview

Our portfolio of novel antifolate compounds was originally developed by Dr. M. Gopal Nair and licensed to us in 2004. A library of orally available and metabolically inert antifolate compounds with potent autoimmune, anti-inflammatory and anti-tumor properties, these compounds are engineered to treat a broad range of

immunological disorders with less harmful and unpleasant side effects than those typically associated with classical antifolates. Diseases that may potentially be treated with metabolically inert antifolates include rheumatoid arthritis, psoriasis, inflammatory bowel disease, cancer and other immunological disorders.

Rheumatoid arthritis is a chronic inflammatory disease that leads to pain, stiffness, swelling and limitation in the motion and function of multiple joints. If left untreated, rheumatoid arthritis can produce serious destruction of joints that frequently leads to permanent disability. Though the joints are the principal body part affected by rheumatoid arthritis, inflammation can develop in other organs as well. The disease currently affects over two million Americans, almost 1% of the population, and is two to three times more prevalent in women. Onset can occur at any point in life with most patients developing the disease between the ages of 35 and 50.

Product Description

CH-1504, the lead product candidate in our antifolate portfolio, potently inhibits dihydrofolate reductase, an enzyme required for cell proliferation. Preclinical and clinical data to date support CH-1504's superior safety and tolerability profile, as well as possible enhanced potency versus methotrexate or MTX, currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases.

CH-1504 is a unique antifolate that we believe might have clinical advantages over MTX as it might have superior efficacy, less toxicity and increased tolerability. Potential advantages of CH-1504 over existing therapies include:

- higher response rate, including efficacy in patients that have failed MTX therapy;
- faster onset of action;
- better tolerability; and
- superior toxicity profile.

The rationale and scientific data to date indicate that CH-1504 might be more tolerable than other rheumatoid arthritis drugs currently on the market. For example, toxicity is a major factor limiting MTX's long-term use in treating rheumatoid arthritis. CH-1504, on the other hand, appears to be devoid of the toxicities related to the formation of metabolites. CH-1504 is a metabolism-blocked antifolate with significant pre-clinical data that indicates enhanced safety and tolerability due to the lack of metabolism. Liver and kidney toxicity is manifested frequently during MTX therapies for rheumatoid arthritis, psoriasis, other immunological diseases and cancer and it has been reported that the metabolic byproducts of MTX may play a significant role in these toxicities.

We believe that in rheumatoid arthritis patients, CH-1504 might have significant clinical advantages over MTX due to its metabolic stability. Because of this stability, it can be hypothesized that in those patients who are unresponsive to MTX, CH-1504 might be clinically efficacious since it is not deactivated by these enzymatic processes.

Clinical Development

In June 2005, we commenced Phase I single and multiple dose escalation clinical trials of CH-1504 in healthy volunteers. These trials were conducted at Guy's Hospital in London under the Clinical Trial Authorization, issued by the Medicines and Healthcare Products Regulatory Agency, the United Kingdom's health authority. The in vivo portion and preliminary analysis of these trials were completed in December 2005.

Continuing evaluation of these results in light of additional preclinical data suggested that the bioavailability of CH-1504 was low and had significant pharmacokinetic variability. Discussions among our personnel, external consultants and potential partners suggested the bioavailability of CH-1504 could be improved through standard

alterations to the formulation. Consequently, we engaged in a comprehensive screening of approximately 25 commercially viable salts and, based on the results of that screening process, selected a disodium salt of CH-1504 to take forward. Having selected a salt formulation, we initiated complimentary pharmaceutical enhancements to the compound that include evaluation of various solid dosage form options. The primary goal of these formulation efforts was to improve the solubility of the compound, increasing bioavailability and reducing pharmacokinetic variation of CH-1504. A formulation using gelucire to increase solubility was selected.

Following the reformulation of CH-1504, we initiated human bioequivalence studies to determine a comparable dose range for global Phase II trials in rheumatoid arthritis. These studies included 3 parts:

- Part A: Dose Finding
- Part B: Two-way, cross-over to establish comparability
- Part C: 7-day, repeat-dose, focused on safety, tolerability and pharmacokinetics of the 3 doses planned to take forward to phase II

The study showed 1.0 mg of the new formulation to be comparable to 15.0 mg of the original free acid formulation and demonstrated an 11.4-fold improvement in relative bioavailability, as measured by area under the curve with an 8.9-fold increase in peak plasma levels (C_{max}).

Based on these studies, in January of 2008 we initiated a Phase II proof of concept study for CH-1504 in rheumatoid arthritis. The study is a multi-national, 12-week double-blind and randomized study in Russia, Ukraine, Poland and Canada with 200 MTX-naïve rheumatoid arthritis patients. The 4-arm trial includes 0.25, 0.5 or 1.0 mg daily dose of CH-1504 vs. 20 mg weekly dose of MTX. Efficacy will be evaluated using standard ACR 20/50/70 scores. Tolerability will be evaluated in two ways: Standard GI adverse events will be grouped and abnormal lab results from liver function tests will be tracked. Interim data safety monitoring (DSM) data is expected in the second half of 2008 with trial results expected in the first half of 2009.

Other Potential Indications for CH-1504 and our Antifolate Portfolio

As we proceed in our clinical development of CH-1504 for rheumatoid arthritis, we expect to continue our evaluation of its potential in other indications. Additional potential indications for CH-1504 include psoriasis, inflammatory bowel disease, psoriatic arthritis and several different kinds of cancer. As CH-1504 advances in rheumatoid arthritis and psoriasis, we will begin to focus on the timing of clinical programs for CH-1504 and/or other of our antifolate compounds in these additional indications. Notwithstanding the foregoing, because of our limited funding, clinical studies will initially be pursued in rheumatoid arthritis, followed conditionally by psoriasis.

Pre-clinical studies conducted at the National Cancer Institute have indicated that our metabolism-blocked antifolates might have better anti-cancer therapeutic activity than MTX. It is believed that our antifolates enter cells by the reduced folate carrier, or RFC, transport system pathway and might be transported up to 4.5 times more efficiently than MTX. CH-1504 has exhibited promising anti-tumor activity in multiple models using a wide variety of cell lines and tumor types. In addition, CH-1504 is active in anti-tumor models known to be resistant to classical polyglutamylated antifolates such as MTX. Collectively this data suggests that CH-1504 is a metabolism-blocked classical antifolate that might be superior to MTX in these diseases. We are currently investigating several of our novel metabolism-blocked antifolates in "in vitro" and "in vivo" assays to select the best candidate to develop for cancer indications.

Antifolate Competition

There are many different drugs that are used to treat rheumatoid arthritis, including hormones, small molecules and biologics, which are manufactured using recombinant technology. The normal course of therapy

for rheumatoid arthritis begins with analgesics, such as aspirin, and non-steroidal anti-inflammatory agents, followed by disease modifying anti-rheumatic drugs (DMARDs), including low dose steroids, MTX, DHODH inhibitors and biologics, and, finally, reconstructive joint surgery for patients failing all therapies. DMARDs are the only drugs that have been shown to alter the course of disease.

We believe that because of its possible low toxicity profile and increased effectiveness, CH-1504 might replace MTX and penetrate the non-steroidal anti-inflammatory drug (NSAID) and biologic markets, giving it the potential to become a widely prescribed therapy for rheumatoid arthritis. Medical practitioners prescribe NSAIDs because of their low toxicity. However, if CH-1504's safety profile and anti-rheumatic effect are superior to MTX, doctors might initiate CH-1504 earlier in the course of treatment than currently prescribed antifolates. The emerging treatment paradigm for medical practitioners is to move patients from NSAIDs to DMARDs early in the disease to improve long-term clinical outcomes as measured by a reduction in joint destruction. The availability of a DMARD that is safer and better tolerated might be expected to encourage this approach. Also, because CH-1504 might not develop treatment resistance (related to metabolism differences) and might be better tolerated, it might delay or decrease the use of expensive biologics in the early stage of the disease. Additionally, as seen with MTX, medical practitioners might administer CH-1504 in combination with biologics as the disease progresses.

The hypothesized efficacy and safety profile of CH-1504 would potentially make it an attractive alternative to existing antifolate and biologic therapies for inflammatory and oncological diseases. We believe CH-1504 can achieve market share not only as a monotherapy at the expense of existing and established products, but also as a therapy prescribed in combination with biologics. Some of the products CH-1504 would compete with include MTX, Johnson & Johnson's Remicade®, Amgen's Enbrel®, Abbott Laboratories' Humira® and Aventis' Arava®.

Currently Available Antifolates. MTX, a classical antifolate, was originally used as a chemotherapy drug to treat certain kinds of cancer, but was also found to be beneficial in treating inflammatory arthritis and psoriasis. MTX is generic and marketed in both injectable and oral formulations by multiple companies including Barr Laboratories, Boehringer Ingelheim Pharma, Mayne Pharma and Mylan Laboratories.

Currently Available Biologics. Although there have been positive results for biologics, we believe physicians are likely to reserve anti-tumor necrosis factor (anti-TNF) and other biologic therapies for patients who have failed initial MTX monotherapy. Despite increased aggressiveness of treating physicians and easier reimbursement, front line use or combination therapy with multiple biologics is unlikely to occur due to their high costs and side effect profile. Enbrel®, Humira® and Remicade® are TNF blockers that have been approved by the FDA over the last six years and are the top selling biologics for rheumatoid arthritis. These three TNF blockers are administered to patients by injection and can be used alone or in combination with other DMARDs or NSAIDs such as aspirin or ibuprofen. Enbrel®, which is developed by Amgen, is the top selling biologic for rheumatoid arthritis, and is also indicated for juvenile rheumatoid arthritis, early rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. Enbrel® had global sales of \$2.9 billion in 2006. Remicade® is a chimeric anti-TNF monoclonal antibody developed by Johnson & Johnson for the treatment of rheumatoid arthritis and Crohn's disease with combined global sales of \$3.0 billion in 2006. Abbott Laboratories' Humira® had 2007 global sales of \$3.0 billion. Both Remicade® and Humira® contain black box warnings for tuberculosis. Rituxan is currently marketed by Genetech and Roche for rheumatoid arthritis in patients refractory to other DMARD therapy. Orencia® (abatacept), developed by Bristol-Myers Squibb, is being studied as a once-monthly infusion for rheumatoid arthritis. The drug has been recently approved by the FDA and earlier data, as reported by Bristol-Myers Squibb, has shown the drug to be safe as a monotherapy and combination.

DMARDs in Development. Rigel Pharmaceuticals' R788 showed proof of concept in a Phase II Clinical Trial in rheumatoid arthritis as announced during 2007. An oral syk kinase inhibitor, R788 (tamatnib fosdium) demonstrated statistically significant results in treating rheumatoid arthritis patients. We believe that with significant ACR scores and good tolerability as observed in this clinical trial, and with the benefit of oral delivery, R788 may be a favorable alternative to the currently approved biological agents. However we anticipate

that, like other biologics, this compound will work best in combination with MTX and should not significantly impact the opportunity available to our antifolate portfolio. Celltech is currently developing CDP-870, a pegylated anti-TNF antibody for the treatment of rheumatoid arthritis and Crohn's disease. CDP-870 is currently in Phase III studies as a monotherapy and in combination with MTX.

Antifolate Marketing

Given the size of the rheumatoid arthritis market, the vast sales forces required to compete in this market, and the necessary infrastructure required, our marketing strategy for CH-1504 is likely to include contracting with or licensing to third parties, particularly for territories outside the United States. It is possible that we might directly commercialize or co-promote this or another of our antifolate compounds in the smaller therapeutic indications such as psoriasis or irritable bowel disease. Out-licensing arrangements might be negotiated and entered into prior to one or more of our antifolate drug candidates being approved for marketing.

I-3D PORTFOLIO

Overview

In May of 2006, we signed an agreement with Active Biotech for the co-development and commercialization of the I-3D portfolio, a group of orally active compounds that inhibit the enzyme dihydroorotate dehydrogenase (DHODH) for the treatment of autoimmune diseases and transplant rejection. At the time of the agreement, Active Biotech had already isolated more than 15 compounds and conducted extensive preclinical modeling resulting in the identification of two potential lead compounds. Pursuant to the agreement, a joint development committee was established to direct the continued development of I-3D compounds with the initial objective of selecting a lead compound with which to initiate Phase I clinical trials.

Having previously demonstrated proof of concept in both rheumatoid arthritis and transplant rejection in animal models, the joint development committee selected AB-224050 as the first I-3D compound to undergo IND-enabling toxicology studies during the third quarter 2006. As part of the ongoing evaluation and preparation for Phase I trials, the joint development committee initiated a Phase 0 (micro-dosing) study to evaluate the half-life of AB-224050 in humans in the first quarter of 2007. Based on the results of the micro-dosing study and other ongoing preclinical activity, it has now been determined that, while demonstrating a significantly shorter half-life than Arava®, AB-224050 will require additional work prior to the commencement of Phase I clinical trials. In 2007, the joint development committee continued preclinical optimization of AB-224050 and conducted further comparisons of AB-224050 versus other compounds in the I-3D portfolio and we will continue to review available compounds and related opportunities during 2008.

I-3D Additional Indications

In addition to therapeutic applications in rheumatoid arthritis, compounds from the I-3D portfolio are believed to have broad clinical application in immune-mediated inflammatory disorders including transplant rejection, psoriasis and systemic lupus erythematosus.

I-3D Competition

As discussed in conjunction with our antifolate program, there are many different drugs that are used to treat rheumatoid arthritis, including hormones, small molecules and biologics, which are manufactured using recombinant technology. The normal course of therapy for rheumatoid arthritis begins with analgesics, such as aspirin, and non-steroidal anti-inflammatory agents, followed by disease modifying anti-rheumatic drugs or DMARDs, including MTX, DHODH inhibitors, low dose steroids and biologics, and, finally, reconstructive joint surgery for patients failing all therapies. DMARDs are the only drugs that have been shown to alter the course of disease.

Leflunomide (Arava®), first marketed in 1998 as an oral DMARD for the treatment of rheumatoid arthritis, is a cytotoxic that is believed to work by inhibiting the DHODH enzyme to prevent DNA synthesis and limit abnormal cell proliferation. Leflunomide is known to have a half-life of greater than two weeks. Given the length of time required to reach therapeutic levels, a higher dose (loading dose) is initially required before dropping down to a lower maintenance dose. Side effects include diarrhea (27%), dyspepsia (10%) abdominal pain (5%), or nausea (13%) and altered liver function (10%).

I-3D Marketing

Our agreement with Active Biotech provides us with the exclusive North and South American commercial rights to all drugs within the I-3D portfolio, while Active Biotech retains rights for the remaining global markets. In addition to sharing development costs, both parties have agreed to pay the other royalty payments on sales in their respective markets. Given the size of the rheumatoid arthritis market, the vast sales forces required to compete in that market, and the necessary infrastructure required, our marketing strategy for I-3D compounds would likely be similar to that of our strategy for CH-1504 and may include contracting with or licensing to third parties. It is possible that, at some point, we might co-promote in the larger therapeutic markets such as rheumatoid arthritis or market I-3D compounds on our own accord for indications other than rheumatoid arthritis. Any such arrangements might be negotiated and entered into prior to one or more of our I-3D drug candidates being approved for marketing.

Scientific Advisory Boards

We retain the services of certain qualified individuals on our Scientific Advisory Boards which normally meet at least yearly. Meetings or consultations with Scientific Advisory Board members are held more often when significant developments arise or new information becomes available that require expert review. The boards provide an opportunity to review our scientific, research and clinical development plans from the perspective of experts and key opinion leaders in the medical community. Specifically, the Scientific Advisory Boards provide advice concerning the design of clinical research protocols to be utilized for the development of our drug candidates and they provide an opportunity to test the validity of our assumptions regarding the attitudes of the medical community relative to various drug characteristics that might be highlighted during development.

Our Scientific Advisory Board for NOH consists of the following individuals:

Horacio Kaufmann, MD is currently the F.B. Axelrod Professor of Neurology and Professor of Medicine and Pediatrics at the New York University School of Medicine. He is the director of the Dysautonomia Research Laboratory at the New York University Medical Center. Dr. Kaufmann is the past President of the American Autonomic Society, former Chairman of the Autonomic Nervous System Section of World Federation of Neurology and the American Academy of Neurology and co-Editor-in-Chief of Clinical Autonomic Research. He is a world renowned expert in the treatment of autonomic disorders, autonomic physiology and pathophysiology. Dr. Kaufmann has published extensively in the medical literature, particularly on the treatment of orthostatic hypotension in neurodegenerative disorders, such as Parkinson's disease and multiple system atrophy. His research on autonomic disorders has been funded by the National Aeronautics and Space Administration, the National Institute of Health, National Organization of Rare Disorders, the DANA foundation and the Dysautonomia Foundation.

Roy Freeman, MD is Professor of Neurology at Harvard Medical School and director of the Center for Autonomic and Peripheral Nerve Disorders in the Department of Neurology at Beth Israel Deaconess Medical Center in Boston, Massachusetts. Dr. Freeman's clinical and research expertise is in the physiology and pathophysiology of the autonomic nervous system and small nerve fibers. He is also an authority on the neurological complications of diabetes, the autonomic complications of Parkinson's disease and multiple system atrophy, the diagnosis and treatment of autonomic and peripheral nervous system disorders and neuropathic pain. Dr. Freeman is widely published in these research areas.

Phillip Low, MD is past chairman of the division of neurophysiology at the Mayo Clinic in Rochester, Minnesota. He is founder and director of the Autonomic Laboratory which evaluates autonomic function. He serves as director of the Mayo Autonomic Disorders Project, the first program grant for autonomic disorders to be funded by the National Institutes of Health. His research is focused on studies of the pathophysiology of orthostatic intolerance and its amelioration. Diseases studied include multiple system atrophy, autoimmune autonomic neuropathy and postural tachycardia syndrome. Dr. Low is Associate Editor of the journal *Autonomic Neuroscience*. He also serves on the editorial board of numerous publications including *Muscle & Nerve*, *Autonomic Neuroscience*, *Journal of Clinical Neurophysiology* and *Journal of Clinical Neuromuscular Diseases*. He also serves on the scientific advisory board of the Neuropathy Association and is a member of the steering committee NIDDK/NHLBI Animal Models of Diabetic Complications Neuropathy Disease Validation Committee.

Peter LeWitt, MD is Professor of Neurology and Psychiatry at Wayne State University School of Medicine in Detroit, Michigan. He is a specialist in Parkinson's disease and other movement disorders and also directs a laboratory research program investigating neurochemical mechanisms and diagnostic markers in Parkinson's and Alzheimer's diseases. He has served as a scientific review consultant for the National Institutes of Health and the Veterans Administration. Other advisory affiliations with national organizations include the International Essential Tremor Foundation and the National Parkinson Foundation. Dr. LeWitt further serves as president of the Michigan Parkinson Foundation. He has been a steering committee member and clinical investigator for the Parkinson Study Group and other clinical trials research consortia. Dr. LeWitt is editor-in-chief of *Clinical Neuropharmacology* and also serves on the editorial board of the *Journal of Neural Transmission*.

Our Scientific Advisory Board for rheumatology consists of the following individuals:

Lee Simon, M.D. is an Associate Professor of Medicine at the Harvard School of Medicine and also on staff at the New England Baptist Hospital and Beth Israel Deaconess Medical Centre. He has been a rheumatologist for 25 years and is a fellow of the American College of Physicians and the American College of Rheumatology. Dr. Simon received his M.D. from the University of Maryland, completed his internship and residency in internal medicine at the Johns Hopkins Hospital, and trained in the arthritis unit of the Massachusetts General Hospital and Harvard Medical School. In addition to his many academic appointments, Dr. Simon has been a consultant to and a senior member of the FDA where he served as Division Director for analgesic, anti-inflammatory and ophthalmologic drug products. Dr. Simon has served on the editorial boards of multiple journals, has authored more than 110 original publications, review articles, and chapters, and has served as an editor of four books.

Vibeke Strand, M.D. is an Adjunct Clinical Professor in the Division of Immunology and Rheumatology at Stanford University School of Medicine. Dr. Strand earned her M.D. at the University of California San Francisco School of Medicine. She completed a residency in Internal Medicine at Michigan State and a Fellowship in Rheumatology/Immunology at the University of California San Francisco School of Medicine. Dr. Strand has been an invited speaker at FDA Arthritis Advisory Committee meetings discussing Guidance Documents for various topics from 1996 through 2003. She has authored over 100 articles and 25 chapters, and has co-edited several books.

Arthur F. Kavanaugh, M.D. is a Professor of Medicine at the University of California, San Diego (UCSD) School of Medicine. In addition, he is the Director of the Center for Innovative Therapy of the UCSD Division of Rheumatology, Allergy, and Immunology. Dr. Kavanaugh earned his BS in biology at the Massachusetts Institute of Technology in Cambridge, Massachusetts and his M.D. at Saint Louis University School of Medicine in Saint Louis, Missouri. He completed a residency in Internal Medicine and then a fellowship in Clinical Immunology/Allergy at the Baylor College of Medicine in Houston, Texas. Dr. Kavanaugh also completed a Rheumatology fellowship at the University of Texas Southwestern Medical School in Dallas. Dr. Kavanaugh has authored more than 120 scientific publications and book chapters. He is on the editorial board for several journals, and has served as peer reviewer for more than a dozen scientific journals. Dr. Kavanaugh is a fellow of the American Academy of Allergy, Asthma, and Immunology, and the American College of Rheumatology, or ACR. He has been a member of and chaired a number of committees in these organizations.

Joel M. Kremer, M.D. is a Professor of Medicine at the Albany Medical College and is also Director of Research at The Center for Rheumatology in Albany. Dr. Kremer earned his M.D. from Temple University School of Medicine and trained in Internal Medicine and Rheumatology at Albany Medical College. He has worked extensively with methotrexate and combinations of new agents with methotrexate. Dr. Kremer is the recipient of the Engalaticheff Award given by The Arthritis Foundation for "contributions which improve the quality of life of patients with arthritis" in 1997. He is the author of approximately 100 peer-reviewed publications, 16 chapters and six texts. He is president and founder of CORRONA, a research organization which gathers data from rheumatologists and patients throughout the United States.

Stanley B. Cohen, M.D. is a Clinical Professor in the Department of Internal Medicine at Southwestern Medical School and in private practice at Rheumatology Associates in Dallas, Texas. He is also Clinical Attending for the Internal Medicine Residency Program and Associate Director of the Arthritis Division at St. Paul Medical Center; Director of the Osteoporosis Center at Baylor Irving Hospital; and Medical Director of Radiant Research Dallas. Dr. Cohen received his M.D. from the University of Alabama School of Medicine and completed an internship and residency in internal medicine at Parkland Memorial Hospital in Dallas. He received his fellowship in rheumatology from St. Paul Medical Center/Southwestern Medical School. Dr. Cohen's current professional appointments also include serving as a Member of the Board of the ACR, the Medical Advisory Board of Directors of the Harold C. Simmons Arthritis Center at Southwestern Medical School and member of the UTSWMC CME Executive Committee. Dr. Cohen is a co-editor of the monograph *The Spondyloarthropathies, Advances in Inflammation Research* and author or coauthor of book chapters, articles and abstracts that have been published in many leading journals and presented at national and international medical and scientific symposia. He has been the recipient of numerous awards and honors including the AF Medical Profession Award.

Edward C. Keystone, M.D. is a Professor of Medicine at the University of Toronto and a Senior Consultant in Rheumatology at Mount Sinai Hospital. Dr. Keystone recently established The Rebecca Macdonald Centre for Arthritis and Autoimmune Disease, which is devoted to research into genomics, therapeutics, and outcomes in autoimmune inflammatory joint disease. Dr. Keystone obtained his M.D. and specialty degrees and fellowships in both Rheumatology and Internal Medicine from the University of Toronto. He then carried out his research training at the Clinical Research Centre in Harrow, London, United Kingdom. He was on staff as a consultant rheumatologist at The Wellesley Central Hospital, Toronto from 1976 to 1998. He is the author of more than 145 peer-reviewed papers, reviews and book chapters, and has been the recipient of numerous teaching awards and honors, including the Senior Investigator Award of the Canadian Rheumatology Association.

William Schwieterman, M.D. is a board-certified internist and rheumatologist who currently works as an independent consultant for biotech and pharmaceutical companies. Dr. Schwieterman received his M.D. from the University of Cincinnati and his internship and residency programs were completed at Mt. Sinai Hospital in New York City. Dr. Schwieterman's research training was obtained at the National Institutes of Health in Bethesda, Maryland. He subsequently joined the FDA in the Centre for Biologics as Chief of the Medicine Branch, and then as Chief of the Immunology and Infectious Disease Branch in the Division of Clinical Trials in CBER, where he worked with sponsors for the development of new agents for pulmonary medicine, neurology, sepsis, hepatitis, rheumatology, infectious disease, solid organ transplantation and wound-healing, among other areas. Dr. Schwieterman is widely published in peer-reviewed journals, in addition to having helped author the FDA's Good Review Practices for investigational products.

Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other activities, for our potential products are extensively regulated by governmental authorities in the United States and other countries. Satisfaction of FDA requirements or requirements of state, local and foreign regulatory agencies typically takes several years, and the actual time required can vary substantially based upon the type, complexity and novelty of the pharmaceutical product. Satisfaction of these requirements will impose costly procedures upon our activities, and we cannot be certain that the FDA or any other regulatory agency will grant approval for any of our products under development on a timely basis, if at all.

Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Failure to comply with the applicable requirements might subject us to administrative or judicial sanctions in the United States, such as the FDA's refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution. Even if a product receives regulatory approval, the approval might be significantly limited to specific indications or uses. After regulatory approval is obtained, later discovery of previously unknown problems with a product might result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

Drug Approval Process in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. None of our drugs may be marketed in the United States until the drug has received FDA approval. The steps required before a drug might be marketed in the United States include:

- preclinical laboratory tests, animal pharmacology and toxicology studies, and formulation studies;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials might begin in the United States;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMPs; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials might begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases might overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. The normal clinical trial phases are:

- Phase I usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness.

- Phase II usually involves trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks, and evaluate preliminarily the efficacy of the drug for specific indications.
- Phase III trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that phase I, phase II, or phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, clinical trials might be suspended by us or the FDA at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort, and financial resources. The agencies review the application and might deem it to be inadequate to support the registration and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA might also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that might be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, that the review time will be reduced.

Section 505b2 of the FDCA allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or data used by FDA in the approval of other drugs. This procedure potentially makes it easier for generic drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless the manufacturing site is cGMP compliant. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA might issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA might require post-marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before we can market our product candidates for additional indications, we must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements

Often, even after a drug has been approved by the FDA for sale, the FDA might require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval

conditions are not satisfied, the FDA might withdraw its approval of the drug. In addition, holders of an approved NDA are required to:

- report certain adverse reactions to the FDA;
- comply with certain requirements concerning advertising and promotional labeling for their products; and
- continue to have quality control and manufacturing procedures conform to cGMP after approval.

The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities, including an assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. We intend to use third party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections might identify compliance issues at the facilities of our contract manufacturers that might disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval might result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Orphan Drug Designations

The FDA can grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, which it might not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not necessarily convey an advantage in, or shorten the duration of, the review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the FDA will not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years. Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication.

Regulations Outside the United States

Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that might be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product.

In Europe, marketing authorizations may be submitted via a centralized, or decentralized (or national level) approach. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

Manufacturing

We own no manufacturing facilities, quality control laboratories or warehouses for storage and distribution. We use third-party contractors for manufacturing drug substances under development. We also use contractors for preformulation, formulation and analytical development as well as manufacturing of drug products used for clinical studies. If any of our products are approved by the FDA for marketing, we plan to use third-party contractors for producing the commercial product. This strategy enables us to direct our financial resources to product development without devoting resources to the time and costs associated with building manufacturing plants and laboratories. We plan on implementing this strategy for the foreseeable future to increase the speed of product development and commercialization.

Intellectual Property

We actively seek to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other key markets. Our goal is to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates, including CH-1504 and droxidopa, and any future product candidates and proprietary technologies through a combination of contractual arrangements and patents, both in the United States and other countries.

As of February 2008, our patent estate for the antifolate portfolio, including CH-1504, includes one issued U.S. patent, two pending U.S. patent applications, a pending Patent Cooperation Treaty (PCT) patent application and several related patent applications pending in countries outside the United States, including Europe and Japan. The issued U.S. patent is U.S. Patent No. 5,912,251, issued June 15, 1999 and entitled "Metabolically Inert Anti-Inflammatory and Anti-Tumor Antifolates". The first pending U.S. patent application is U.S. patent application number US 2006-0111272. The second pending U.S. patent application and the pending PCT patent application are directed to certain new antifolate compounds.

The issued U.S. patent covers our current product candidate, CH-1504, as well as certain analogues of CH-1504, including claims to these compounds as compositions of matter, in pharmaceutical formulations and for use in treatment of certain diseases. The pending U.S. patent applications and international PCT applications expand our proprietary position, claiming additional compounds and their uses as well as new uses of CH-1504. We plan to continue to strengthen our patent estate on our antifolate portfolio by filing and pursuing additional patents.

Our patent estate for droxidopa includes seven pending U.S. patent applications and one PCT patent application directed to pharmaceutical compositions comprising droxidopa and therapeutic methods of treatment using droxidopa. We plan to continue to strengthen our patent estate on droxidopa by filing and pursuing additional patents.

The patent estate for the I-3D portfolio includes U.S. patent No. 7,074,831, issued July 11, 2006 and additional patents currently issued and pending, with rights accruing to the Company through the co-development agreement with Active Biotech. We plan to continue to strengthen our patent estate on the I-3D portfolio, in collaboration with Active Biotech, by filing and pursuing additional patents.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents are unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, it is our policy to require all of our employees, consultants, advisors and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Employees

We have attracted and retained a management team with core competencies and expertise in numerous fields, including manufacturing, research, clinical, regulatory and business development. Our management and advisors are comprised of experienced pharmaceutical and biotechnology industry veterans and respected experts. We are led by our Chief Executive Officer, Dr. Simon Pedder, formerly Vice President, Pharmaceutical Business, Oncology at Hoffmann-La Roche Inc., who has over 16 years of senior pharmaceutical management experience, including drug development and business experience. During this time at Roche, Dr. Pedder was responsible for a number of global development programs, successful registrations and product launches.

We have a total of thirteen (13) employees. We believe the relationships with our employees are satisfactory. We anticipate that we will need to identify, attract, train and retain other highly skilled personnel. Hiring for such personnel is competitive, and there can be no assurance that we will be able to retain our key employees or attract, assimilate or retain the qualified personnel necessary for the development of our business.

Where you can find additional information

Our website address is www.chelseatherapeutics.com. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC.

Executive Officers of the Registrant

The following table sets forth the name, age and position of each of our executive officers and directors as of March 10, 2008.

Name	Age	Position
Simon Pedder	47	President, Chief Executive Officer and Director
J. Nick Riehle	55	Vice President, Administration and Chief Financial Officer
L. Arthur Hewitt	54	Vice President, Drug Development
Keith Schmidt	57	Vice President, Sales and Marketing

Simon Pedder, Ph.D.—President, Chief Executive Officer and Director. Dr. Pedder joined us from Hoffmann-La Roche Inc. in April 2004 where he was Vice President of Pharmaceutical Business, Oncology and an executive officer since February 2003. Prior to that he served as the Vice President, Drug Development at Shearwater Corporation from May 2001 until December 2002. Prior to that Dr. Pedder served in a number of positions at Hoffmann-La Roche, including as Director, Pharmaceutical Business, Pharmaceutical Development and Project Management from May 1994 until May 2001. While at Hoffmann-La Roche, Dr. Pedder was in charge of the development of Pegasys and Copegus, which have combined annual worldwide sales of over \$1 billion, and oversaw a number of successful NDAs. Dr. Pedder has his Ph.D. in Pharmacology from the College of Medicine at the University of Saskatchewan in Canada.

J. Nick Riehle, MBA—Vice President, Administration and Chief Financial Officer. Mr. Riehle has been our Vice President, Administration and Chief Financial Officer since July 2004. Prior to that he served as Chief Financial Officer at HAHT Commerce, Inc., a software company, from August 1996 until June 2003 and as an independent contractor from July 2003 until July 2004. Prior to that, Mr. Riehle served in various roles at Nortel Networks and IBM. Mr. Riehle has his Bachelor of Commerce from McGill University, his MBA from York University and earned a Certified Management Accountant (CMA) designation from Ontario, Canada.

L. Arthur Hewitt, Ph.D.—Vice President, Drug Development. Dr. Hewitt has been our Vice President, Drug Development since May 2004. Prior to that he served as an independent contractor from January 2003 to

May 2004, as Director of Scientific Affairs at Shearwater Corporation, a drug delivery company, from October 2002 until January 2003 and as Director of Scientific Affairs for Amgen Canada from July 1991 until November 2000. During his years at Amgen, Dr. Hewitt oversaw the approval of Neupogen, Stemgen and Infergen. Dr. Hewitt obtained his Ph.D. in Pharmacology from the Medical School at the University of Montreal.

Keith Schmidt—Vice President, Marketing and Sales. Mr. Schmidt has served as our Vice President, Marketing and Sales since July 2006. In February 2007, Mr. Schmidt was named an executive officer of the Company. Prior to that he was President of his biotech consulting company, Tellico Pharma LLC from June 2005 and served as Vice President of Thomson Healthcare Advanced Therapeutics Communications, a medical education company, from February 2002 until May 2005. From 1996 until January 2002, Mr. Schmidt served as an International Business Leader for Hoffmann-La Roche where he developed and led the global sales and marketing launch efforts for Pegasys and Copegus. Mr. Schmidt earned a Bachelor of Science from South Dakota State University and an MBA from the University of San Francisco.

ITEM 1A. RISK FACTORS

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report and in any documents incorporated in this report by reference.

We are a development-stage company and might not be able to commercialize any product candidates.

We are a development-stage company and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, negotiating in-licensing agreements with our partners, acquiring, developing and securing our proprietary technology, participating in regulatory discussions with the FDA, the EMEA and other regulatory agencies and undertaking pre-clinical trials and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We currently have no product revenue and will need to raise additional capital to operate our business.

To date, we have generated no product revenue. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenue. Currently, our primary product candidates are droxidopa and CH-1504, and neither is approved by the FDA nor, with the exception of droxidopa which has Japanese approval, any other regulatory agency for sale. Therefore, for the foreseeable future, we will have to fund all of our operations and development expenditures, including anticipated 2008 expenses of approximately \$40 million, from cash on hand, other equity or debt financings, licensing fees and grants. If needed, we may seek additional sources of financing, which might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might not be able to complete planned pre-clinical and clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing could involve the issuance of our equity securities, which would have a dilutive effect on our stockholders.

We are not currently profitable and might never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we might never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future and might never become profitable. From inception through December 31, 2007 we had losses of \$34.7 million, and we anticipate losses in the range of \$38 to \$60 million during the 12 to 18 months commencing January 2008. Actual losses will depend on a number of considerations, including:

- the pace and success of pre-clinical development and clinical trials for droxidopa, antifolates and other product candidates;
- seeking regulatory approval for our various product candidates;
- discussions with regulatory agencies concerning the design of our clinical trials
- our ability to identify and recruit patients into our clinical trials at costs consistent with our current estimates;
- the pace of development of new intellectual property for our existing product candidates;
- possible out-licensing of our product candidates;
- in-licensing and development of additional product candidates;
- implementing additional internal systems and infrastructure; and
- hiring additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and development expenditures. As a result, we will need to generate significant revenue in order to achieve and maintain profitability. We might not be able to generate revenue or achieve profitability in the future and are unlikely to do so in the near term. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

We might not obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize our product candidates including droxidopa, CH-1504, or any other product candidate either currently in our drug candidate portfolio or which we might acquire or develop in the future. We will need FDA approval to commercialize our product candidate in the United States and approvals from equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenue from, a product candidate;
- impose costly procedures on us; and

- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of these product candidates, particularly droxidopa or CH-1504, will severely undermine our business and could substantially extend the period before we have a saleable product, leaving us without any source of revenue until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize product candidates for sale outside the United States.

Our drug candidates may require extensive reformulation work prior to approval or they may prove unsuitable for further development regardless of reformulation efforts.

Our development program for CH-1504 was delayed in May of 2006 as a result of data that came to our attention concerning possible bioavailability issues and animal data suggesting significant variations in blood plasma levels. We have identified and run bioavailability tests on a different formulation of CH-1504 that we believe has improved the drug relative to these issues; however we cannot determine at this time whether these improvements will be adequate to permit FDA and other regulatory approvals. Other formulation issues may arise or prove more significant than anticipated, either with CH-1504 or with other drug candidates in our portfolio.

Our product candidate CH-1504 has had only limited formal clinical trials.

Our product candidate, CH-1504, is in an early stage of development and requires extensive clinical testing. In June 2005, we commenced Phase I dose escalation clinical trials of CH-1504 in humans in the United Kingdom at Guy's Hospital in London, under the Clinical Trial Authorization issued by the Medicines and Healthcare Products Regulatory Agency, the United Kingdom's health authority. Following the recent reformulation program, we began additional clinical testing to ascertain equivalency ratios for the reformulated compound as compared to the compound used during the Phase I trials in the UK. Following this testing we commenced Phase II clinical trials for CH-1504 in rheumatoid arthritis. After the completion of those trials, we may initiate several additional Phase II studies in other indications and, as appropriate, Phase III studies in rheumatoid arthritis with or without a partner. Upon completion of the Phase III studies in rheumatoid arthritis, we hope to use data from these studies to file a New Drug Application, or NDA in the United States. We currently estimate a global filing of the NDA no sooner than 2011. However, at any point during the process we might decide to focus our efforts on a different lead compound, and we cannot predict with any certainty the success or timing of our clinical trials, if or when we might submit an NDA for regulatory approval of this product candidate or whether such an NDA will be accepted.

There has been only very limited testing of our I-3D product candidates.

Our I-3D product candidates being jointly developed with Active Biotech are early in their development. None of the candidates have had adequate toxicology testing in animals to permit clinical testing and there is no clinical evidence of efficacy for any of these candidates, despite limited similarities with compounds currently marketed by others. Animal toxicology trials on our I-3D compounds may not permit further development of these drugs or we may have to carry out toxicology trials on several compounds before we find one that is appropriate for clinical testing, if at all. Once clinical trials are undertaken, the compound or compounds may not prove adequately safe and efficacious in humans and may not be approved by the FDA or other regulatory agencies.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. For example, because we did not receive orphan drug status from the EMEA for droxidopa as a treatment for Parkinson's disease, our clinical trials for that indication might have to be more involved and take longer to complete and get reviewed than otherwise would have been the case. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials might be delayed by several factors, including:

- unforeseen safety issues;
- clarification of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment, including the aggregate of approximately 600 required to complete the four Phase II or Phase III trials that are or are expected to be ongoing in 2008;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unexpected emergence of competitive drugs against which our compounds might compete for clinical trial resources or need to be tested.

In addition, we or the FDA or another governing regulatory agency may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the regulatory agency finds deficiencies in the conduct of these or our regulatory submissions. Therefore, we cannot predict with any certainty the schedule for future clinical trials.

The results of our clinical trials might not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process might fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and might delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenue. Preliminary clinical trials conducted previously on our CH-1504 compound involved a small patient population over a relatively short period and because of these factors, the results might not be indicative of future results. Moreover, these initial trials were not performed in accordance with standards normally required by the FDA and other regulatory agencies.

We intend to explore additional indications for droxidopa, however these programs may not prove successful.

We have announced our interest in exploring certain additional indications for droxidopa and we may make similar announcements in the future. While trials conducted by our partner, Dainippon Sumitomo Pharma Co., Ltd. (DSP), for the Japanese market provide evidence of efficacy for certain indications, other indications may be explored for which we have no existing clinical evidence of efficacy. Such trials are likely to be very costly. We do not have market approval from the FDA or other regulatory agencies for any of the indications we are exploring and there are no guarantees that additional clinical trials will provide new evidence of efficacy in the targeted indications or permit us to gain market approval from regulatory agencies.

Physicians and patients might not accept and use our drugs.

Even if the FDA approves any of our product candidates, physicians and patients might not accept and use them. Acceptance and use of our products will depend upon a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drug;
- cost-effectiveness of our product relative to competing products;
- understanding by prescribing physicians of the medical conditions we are attempting to address;
- availability of reimbursement for our product from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect that sales of our product candidates could, if approved, generate a substantial portion of our product revenue for an extended period, the failure of such a drug to find market acceptance would harm our business and could require us to seek additional financing.

Our drug development program depends upon third-party researchers who are outside our control.

We depend upon independent clinical research organizations, investigators and other collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. They might not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators might also have relationships with other commercial entities, some of which might compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

Our drug development program also depends upon our partners who are outside our control.

We have licensed certain rights related to droxidopa from DSP and depend upon them for data and support in advancing our clinical program for this compound. In addition, DSP is currently the sole manufacturer of this compound for our clinical program. Similarly, we are pursuing the development of the I-3D portfolio with our partner, Active Biotech AB and depend on their cooperation to advance the program and to share the cost of development and testing. Without the timely support of these partners, either program could suffer significant delays, require significantly higher spending or face cancellation.

We rely exclusively on third parties to formulate and manufacture any product candidates.

We have only limited experience in drug formulation and no experience in drug manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. While we have a contract in place with DSP covering droxidopa, we currently have no contract for the commercial scale manufacture of CH-1504 or other antifolates or I-3D compounds. We intend to contract with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our clinical trials. If any of our current product candidates or any other product candidates that we may develop or acquire in the future receive FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We might not be able to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This

approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our contract manufacturers might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue.

We have no experience selling, marketing or distributing products and only limited internal capability to do so.

We currently have no sales, marketing or distribution capabilities other than as provided by our Vice President of Sales and Marketing. We do not anticipate having significant additional resources within the next six months to allocate to the sales and marketing of our proposed products. As a result, our future success depends, in part, on:

- our ability to enter into and maintain collaborative relationships for these capabilities, either through out-licensing of our compounds or through contracting organizations;
- the collaborator's strategic interest in the products under development; and
- such collaborator's ability to successfully market and/or sell any such products.

To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products or if we decide to add internal resources to complement third party resources, significant development expenditures, management resources and time will be required to establish and develop our own marketing and sales force with technical expertise.

If we cannot compete successfully for market share against other drug companies, we will not achieve sufficient product revenue and our business will suffer.

The market for our product candidate CH-1504 is characterized by intense competition and rapid technological advances. The initial market for droxidopa, while smaller, has well established generic competition. Other markets for droxidopa, such as fibromyalgia, are emerging with new and heavily marketed offerings. If CH-1504, droxidopa or other product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products might provide greater therapeutic convenience, efficacy or other benefits for a specific indication than our products or might offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we will not achieve sufficient product revenue and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have compounds already approved or in

development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs;
- launching, marketing and selling drugs; and
- post-marketing safety surveillance.

Developments by competitors might render our products or technologies obsolete or non-competitive.

Companies that currently sell both generic and proprietary compounds for the treatment of rheumatoid arthritis include, but are not limited to, Abbott Laboratories, Amgen, Aventis, Barr Laboratories, Boehringer Ingelheim Pharma, Hoffman—La Roche, Johnson & Johnson, Bristol-Myers Squibb and Mylan Laboratories. Companies that currently sell compounds used for the treatment of orthostatic hypotension include Shire, Mylan Pharmaceuticals, Eon Labs, Impax Laboratories and King Pharmaceuticals. Alternative technologies are being developed to treat rheumatoid arthritis by numerous companies including Rigel and Celltech, which are in advanced clinical trials. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations.

Our success, competitive position and future revenue will depend in part on our ability to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We do not know whether any of our pending patent applications or those patent applications that we may file or license in the future will result in the issuance of any patents. Moreover, we cannot predict the degree of patent protection that will be afforded by those patent applications that do result in issuance. Although we generally seek the broadest patent protection available for our proprietary compounds, we may not be able to obtain patent protection for the actual composition of any particular compound and may be limited to protecting a new method of use for the compound or otherwise restricted in our ability to prevent others from exploiting the compound. If our patent protection for any particular compound is limited to a particular method of use or indication such that, if a third party were to obtain approval of the compound for use in another indication, we could be subject to competition arising from off-label use.

Moreover, our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated, rendered unenforceable or circumvented, any of which could limit our ability to stop competitors from marketing related products. In addition, the rights granted under any issued patents may not provide us with competitive advantages against competitors with similar compounds or technologies. Furthermore, our competitors may independently develop similar technologies in a manner that does not infringe our patents or other intellectual property.

If a third party legally challenges our patents or other intellectual property rights that we own or license, we could lose certain of these rights. For example, third parties may challenge the validity of our U.S. or foreign

patents through reexaminations, oppositions or other legal proceedings. If successful, a challenge to our patents or other intellectual property rights could deprive us of competitive advantages and permit our competitors to use our technology to develop similar products.

In addition, we do not anticipate having patent protection on our droxidopa compound when and if it receives market approval by the FDA. While the orphan drug designation for this compound by the FDA will provide seven (7) years of market exclusivity, we will not be able to exclude other companies from manufacturing and marketing this compound beyond that timeframe.

Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

If a third party were to file a patent infringement suit against us, we could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent infringed, unless we can obtain a license from the patent holder. Any necessary license may not be available on acceptable terms or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we are able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. We also may be required to pay substantial damages to the patent holder in the event of an infringement. If we have supplied infringing products to third parties for marketing or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for any damages they may be required to pay to the patent holder and for any losses they may sustain themselves as a result.

We may initiate patent litigation against third parties to protect or enforce our patent rights. Failure to protect our patents and other proprietary rights may materially harm our business, financial condition and results of operations.

Legal or administrative proceedings may be necessary to defend against claims of infringement or to enforce our intellectual property rights. If we become involved in any such proceeding, irrespective of the outcome, we may incur substantial costs, and the efforts of our technical and management personnel may be diverted, which could materially harm our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that disclosure of some of our confidential information could be compelled and the information compromised. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments that, if perceived as negative by securities analysts or investors, could have a substantial adverse effect on the trading price of our common stock.

Existing patents and proprietary rights could harm our competitive position.

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. In addition, to the extent that a third party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses might not be available or may not be available on commercially reasonable terms, if at all. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, enforceability or scope of our patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors.

Some jurisdictions have laws that permit the government to force a patentee to grant a license to a third party for commercialization of a patented product if the government concludes that the product is not sufficiently developed or not meeting the health needs of the population. Such compulsory licensing laws are very rarely invoked outside of South America and Africa. In addition, a number of countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Because of the extensive time required for development, testing and regulatory review of a new drug, it is possible that any related patent may expire before any of our product candidates can be commercialized or remain in force for only a short period following commercialization. In either case, this would reduce any advantages of the patent.

If we are unable to satisfy our obligations under current and future license agreements, we could lose license rights which would adversely affect our business.

We are a party to a license agreement with M. Gopal Nair under which we license patent rights for our product candidate CH-1504 and other antifolates. Similarly, we license patent and/or certain other rights from Dainippon Sumitomo Pharma Co., Ltd. (DSP) for droxidopa and from Active Biotech AB for the I-3D portfolio of compounds. We may enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various milestone payments, royalty payments and other obligations on us. If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business. If a licensor challenges our license position, our competitive position and business prospects could be harmed.

Our license agreement with Dr. Nair reserves rights to the licensor in India. Therefore, we will not commercialize our antifolates in India. Our license agreement with DSP reserves rights to the licensor in Japan, Korea, China and Taiwan which preclude our commercialization of droxidopa in those markets. Our license agreement with Active Biotech AB grants rights to us only in North America and South America with Active Biotech retaining commercialization rights in the rest of the world.

If we are unable to enforce trade secret protection and confidentiality agreements with our employees, our competitive position might be harmed.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents are unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, it is our policy to require all of our employees, consultants, advisors and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements might not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we might have to:

- obtain licenses, which might not be available on commercially reasonable terms, if at all;

- abandon an infringing drug candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings, which might be costly whether we win or lose, and which could result in a substantial diversion of valuable management resources.

Our ability to generate product revenue will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if a product candidate is approved by the FDA, insurance coverage might not be available and reimbursement levels might be inadequate to cover our drug. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our product, once approved, market acceptance and our revenue could be reduced.

Specifically, not all physicians recognize a separate indication for symptomatic neurogenic orthostatic hypotension and we cannot provide assurances that reimbursement will be approved by the relevant decision makers even if droxidopa receives market approval from the FDA or other regulatory authorities.

Our potential future earnings may be reduced should we decide to out-license one or more of our drug product candidates.

We may decide to out-license one or more of our drug product candidates, reducing future profits available to us. Should we license our antifolate candidates to another pharmaceuticals company, it would allow the partner to market and sell our antifolate compounds in one or more markets around the world. Similarly, while we currently intend to market and sell droxidopa in the United States, we may consider out-licensing it for Europe and other world markets. If either the antifolates or droxidopa are licensed to a strategic partner, the profit available to us may be substantially reduced from what might otherwise be possible should we retain all rights to the products and market and sell them directly.

We might not successfully manage our growth.

We are a small, development stage company. Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. We currently have thirteen (13) employees and anticipate potentially doubling our number of employees over the next 12 months. To manage this growth and address the upcoming expiration of our existing facilities lease, we have located new facilities, negotiated a lease and will need to complete relocation with minimal business disruption. We may also have to augment our operational, financial and management systems and hire and train even more qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities might involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures, and those of our partners, for using, storing, handling and disposing of these materials comply with federal, state, local and, where applicable, foreign laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

As a small, development stage company, we are highly dependent on our executive officers, including particularly our Chief Executive Officer, Simon Pedder, Ph.D., and our principal scientific, regulatory and medical advisors. Dr. Pedder is the only executive officer whose employment with us is governed by an employment agreement, and the term of employment under that agreement expires in May 2009. We do not have "key person" life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

If we are unable to hire additional qualified personnel, our ability to grow our business will be harmed.

As a small, development stage company, we will need to hire additional qualified personnel with expertise in pre-clinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel is critical to our success.

We might incur substantial liabilities and might be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we might incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our products. Although we carry clinical trial insurance, we might not be able to renew such insurance at a reasonable cost, if at all, or our intended collaborators may be unable to obtain such insurance at a reasonable cost, if at all. Even if our agreements with any future collaborators entitle us to indemnification against losses, that indemnification might not be available or adequate should any claim arise.

We may be subjected to unforeseen or unanticipated market conditions that could adversely affect our available working capital and financial position.

We hold positions in short-term investments that consist of certain auction rate securities (ARS). These investments represent interests in collateralized debt obligations supported by pools of student loans with long-term nominal maturities but for which interest rates are normally reset monthly through a dutch auction process. Consistent with our policy, all ARS investments have at least A credit ratings at the time of purchase. However, beginning in February 2008, auctions for the resale of such securities have ceased to reliably support

the liquidity of these securities. We expect to continue to receive interest according to the stated terms of the investments, including above market interest rates related to the auction failures. Although such loss of liquidity will most likely be short-term in nature as a secondary market for the securities emerges or successful auctions resume, we cannot be certain that liquidity will be restored in the foreseeable future, in which case we may be unable to sustain our development programs as currently planned. We may not be able to access cash by selling these securities for which there is insufficient demand without a loss of principal until a future auction for these investments is successful, a secondary market emerges, they are redeemed by their issuer or they mature. If liquidity is not reestablished in the short term, we may also be required to reclassify these investments as long-term assets based on the nominal maturity date of the underlying securities. In addition, the value of such investments could potentially be impaired on a temporary or other-than-temporary basis. If it is determined that the value of the investment is impaired on an other-than-temporary basis, we would be required to write down the investment to its fair value and record a charge to earnings for the amount of the impairment.

The trading volume of our common stock is limited and our investors may encounter difficulties selling significant quantities of our stock without adversely impacting the price at which they can sell.

Since listing with the NASDAQ Stock Market in May 2006, the trading volume for our stock has varied significantly from day to day and often the number of shares traded has been low. No assurance can be given that a more liquid trading market will develop.

The prices at which are shares of our common stock are traded will likely be volatile.

You should expect the prices at which our common stock is traded to be highly volatile. Since the commencement of NASDAQ trading in May 2006, the price has varied from a low of \$2.43 to a high of \$8.10. The expected volatile price of our stock will make it difficult to predict the value of your investment, to sell your shares at a profit at any given time, or to plan purchases and sales in advance. A variety of other factors might also affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delays or failures in initiating, completing or analyzing pre-clinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that might have been unrelated or disproportionate to the

operating performance of individual companies. These broad market and industry factors might seriously harm the market price of our common stock, regardless of our operating performance.

We have never paid dividends and do not intend to pay cash dividends.

We currently anticipate that no cash dividends will be paid on our common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance our future operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease 3,916 square feet of office space in Charlotte, North Carolina. This lease expires on June 30, 2008 and requires us to make monthly payments of approximately \$4,901 through the expiration date. We do not own any real property. We believe that our existing facilities are adequate to meet our needs through the end of the lease period.

On March 7, 2008 we executed a lease for 9,956 square feet of office space in Charlotte, North Carolina near our existing office location to serve as our new corporate headquarters. We anticipate occupancy on or about May 15, 2008 and will have monthly payments, beginning October 15, 2008, of approximately \$19,041. The lease expires on October 15, 2013 and calls for annual rent increases of 3%. In addition, the lease provides an option to rent an additional 3,000 square feet of adjacent space. The option remains in effect until November 2009 at a cost of \$1,750 per month unless terminated sooner at our discretion. A security deposit equal to four (4) months rent or approximately \$76,163 was paid upon signing the lease. We believe that these facilities, including the option space described above, are adequate to meet our needs through 2011.

ITEM 3. LEGAL PROCEEDINGS

We are not subject to any pending legal proceeding, nor are we aware of any threatened claims against us.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2007.

PART II

ITEM 5. MARKET FOR THE REGISTRANTS COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has been traded on the National Association of Securities Dealers Automatic Quotation System ("NASDAQ") under the symbol "CHTP" since May 2, 2006 and traded on the Over-the-Counter Bulletin Board under the symbol "CHTP.OB" from July 29, 2005 through May 1, 2006 and under the symbol "IVRC.OB" from August 18, 2004 through July 28, 2005. The following table sets forth the high and low prices of our common stock, as reported per the appropriate market. These quotations reflect inter-dealer prices, without retail mark-up, markdown, or commission and may not represent actual transactions. Trading on our common stock has been sporadic, exemplified by low trading volume, with 134 of 420 trading days between our listing on NASDAQ and the end of 2007 having fewer than 10,000 shares traded.

	<u>High</u>	<u>Low</u>
Fiscal year ended December 31, 2006		
First Quarter	\$6.25	\$2.81
Second Quarter	\$7.30	\$3.25
Third Quarter	\$4.80	\$2.43
Fourth Quarter	\$4.85	\$3.19
Fiscal year ended December 31, 2007		
First Quarter	\$6.70	\$3.56
Second Quarter	\$7.02	\$5.05
Third Quarter	\$8.10	\$5.09
Fourth Quarter	<u>\$7.80</u>	<u>\$5.80</u>

As of March 7, 2008, the last sale price of our common stock on NASDAQ was \$6.26 per share. As of March 7, 2008, there were approximately 835 stockholders of record.

We have neither paid nor declared dividends on our common stock since our inception and do not plan to pay dividends in the foreseeable future. Any earnings that we may realize will be reinvested to finance our growth.

The market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors, such as fluctuations in our operating results, announcements of technological innovations or new therapeutic products by us or others, clinical trial results, developments concerning agreements with collaborators, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of drugs developed by us or others, future sales of substantial amounts of common stock by existing stockholders and general market conditions, can have an adverse effect on the market price of our common stock.

ITEM 6. SELECTED FINANCIAL DATA.

The following table sets forth financial data with respect to us as of and for the five years ended December 31, 2007 and the period from April 2, 2004 (inception) through December 31, 2007. The selected financial data below should be read in conjunction with the audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7:

	Years ended December 31,					Period from April 3, 2002 (Inception) to December 31,
	2007	2006	2005	2004	2003	2007
	(In thousands, except share and per share data)					
Statement of Operations Data:						
Operating expenses:						
Research and development . . .	\$ 12,336	\$ 6,864	\$ 5,516	\$ 1,809	\$ —	\$ 26,525
Sales and marketing	1,294	642	524	168	—	2,628
General and administrative . . .	2,875	2,028	2,076	1,012	—	7,991
Total operating expenses	16,505	9,534	8,116	2,989	—	37,144
Operating loss	(16,505)	(9,534)	(8,116)	(2,989)	—	(37,144)
Interest and other income (expense), net	1,424	863	200	(28)	—	2,459
Net loss	(15,081)	(8,671)	(7,916)	(3,017)	—	(34,685)
Basic and diluted net loss per share	\$ (0.66)	\$ (0.46)	\$ (0.64)	\$ (0.47)	\$ —	
Shares used to compute basic and diluted net loss per share	22,936,780	18,780,638	12,321,061	6,431,451	5,428,217	

	As of December 31,				
	2007	2006	2005	2004	2003
(in thousands)					
Balance Sheet Data:					
Cash and cash equivalents	\$ 34,076	\$ 3,111	\$ 3,173	\$10,977	\$—
Short-term investments	28,638	12,786	—	—	—
Working capital	57,910	14,080	2,328	10,476	—
Total assets	63,163	16,171	3,427	11,141	—
Deficit accumulated during the development stage	(34,685)	(19,604)	(10,932)	(3,017)	—
Total stockholders' equity	57,967	14,137	2,384	10,541	—

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. This discussion contains predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

We are a development stage pharmaceutical company that seeks to acquire and develop innovative products for the treatment of a variety of human diseases. Our strategy is to develop technologies that address important unmet medical needs or offer improved, cost-effective alternatives to current methods of treatment. Specifically, we are developing prescription products for multiple autoimmune disorders including rheumatoid arthritis, psoriasis, inflammatory bowel disease and cancer along with our development of a novel therapeutic agent for the treatment of neurogenic orthostatic hypotension and related conditions and diseases.

We are currently focusing our drug development resources on three major research and development projects: droxidopa for symptomatic neurogenic orthostatic hypotension and other potential indications; our antifolate compounds, including CH-1504, for rheumatoid arthritis; and the I-3D portfolio of therapeutics we are co-developing with Active Biotech for autoimmune disease and transplantation. Droxidopa, our most advanced investigational product candidate, is an orally active synthetic precursor of norepinephrine. It is being developed for the treatment of neurogenic orthostatic hypotension and is currently approved and marketed in Japan. During 2007, the FDA granted orphan drug status to droxidopa for the treatment of neurogenic orthostatic hypotension and the European Commission granted orphan medicinal product designation for the treatment of patients with Pure Autonomic Failure (PAF) and patients with Multiple Systems Atrophy (MSA). It is currently being studied in double-blind pivotal Phase III trials under a Special Protocol Assessment, or SPA, with the FDA, designed to compare droxidopa to placebo at multiple sites in North America and Europe. It is also being studied in a double-blind, placebo controlled Phase II clinical study for the treatment of intradialytic hypotension. Our lead antifolate candidate, CH-1504, is being investigated for the treatment of rheumatoid arthritis in a Phase II head-to-head clinical trial to compare its efficacy and tolerability against methotrexate, currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases. Our antifolate program is complemented by a strategic partnership with Active Biotech AB for the joint development of a portfolio of therapeutics targeting immune-mediated inflammatory disorders and transplantation.

Since inception we have focused primarily on organizing and staffing our company, negotiating in-licensing agreements with our partners, acquiring, developing and securing our proprietary technology, participating in regulatory discussions with the FDA, the EMEA and other regulatory agencies and undertaking pre-clinical trials and clinical trials of our product candidates. We are a development stage company and have generated no revenue since inception. We do not anticipate generating any revenue until and unless we successfully obtain approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. However, developing pharmaceutical products is a lengthy and expensive process. Even if we do not encounter unforeseen safety issues or timing or other delays during the course of developing our currently licensed product candidates, we would not anticipate receiving regulatory approval to market such products until, at the earliest, 2010. Currently, development expenses are being funded with proceeds from equity financings completed in December 2004, February 2006, March 2007 and November 2007. To the extent we are successful in acquiring additional product candidates for our development pipeline and as we move our products into more extensive clinical trials, our need to finance research and development costs will continue to increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products.

Revenue and Cost of Revenue

We have not generated any revenue from licensing, milestones or product sales through December 31, 2007, and we do not expect to generate revenue within the next 12 to 24 months. We might never be able to generate revenue. None of our existing product candidates are expected to be commercially available until 2010, if at all.

Research and Development

Research and development expenses consist primarily of costs associated with determining feasibility, licensing and pre-clinical and clinical testing of our licensed pharmaceutical candidates, including salaries and related personnel costs, fees paid to consultants and outside service providers for drug manufacture and development, certain legal expenses and other expenses. All of our major research and development projects subject us to drug development and regulatory risks, including specifically risks of delays and cost over-runs that could be material to our financial condition and results of operations. For certain programs, including our antifolates and I-3D portfolio, we rely on collaborative partners or our ability to enter into collaborations on favorable terms in order to advance candidates and pay a portion of the research and development expenses. See "Item 1A. Risk Factors." We expense our research and development costs as they are incurred. Research and development expenses, related to our three major research and development projects, for the years ended December 31, 2007, 2006 and 2005 were approximately \$12.3 million, \$6.9 million and \$5.5 million, respectively, and are detailed as follows:

(in thousands)	Years ended December 31,		
	2007	2006	2005
Antifolates	\$ 4,500	\$3,100	\$5,500
Droxidopa	7,000	2,100	—
I-3D	800	1,700	—
	<u>\$12,300</u>	<u>\$6,900</u>	<u>\$5,500</u>

Sales and Marketing

Selling and marketing expenses consist primarily of salaries and related expenses that support our business development activity, promotional expenses, expenses related to the branding of our pharmaceutical compounds and certain legal expenses.

General and Administrative

General and administrative expenses focus on the support of administrative activities and consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses for such personnel, consulting and professional fees and other corporate expenses, including general legal activities and facilities-related expenses.

Corporate History

On February 11, 2005, we completed a merger with Ivory Capital Corporation, a publicly traded Colorado corporation, in which a wholly owned subsidiary of Ivory Capital was merged with and into Chelsea, and Chelsea became a wholly owned subsidiary of Ivory Capital. The merger resulted in a change of control of Ivory Capital, with the former stockholders of Chelsea owning approximately 96.75% assuming the conversion of all outstanding options and warrants. In addition, the terms of the merger provided that the sole officer and director of Ivory Capital would be replaced by the officers and directors of Chelsea. The transaction was accounted for as a reverse acquisition with Chelsea as the acquiring party and Ivory Capital as the acquired party, in substance, a reorganization of Chelsea. Accordingly, when we refer to our business and financial information relating to

periods prior to the merger, we are referring to the business and financial information of Chelsea unless the context indicates otherwise. On July 28, 2005, Ivory Capital Corporation merged with Chelsea Therapeutics International, Ltd., with Chelsea Therapeutics International, Ltd. as the surviving corporation. As a result, Chelsea Therapeutics International, Ltd. is the public reporting company and is the 100% owner of Chelsea Therapeutics, Inc., its operating subsidiary.

When we refer to business and financial information for periods between January 1, 2005 and July 28, 2005, we are referring to the business and financial information of Ivory Capital Corporation. Except as noted, all share numbers included herein reflect the conversion of every nine shares of Ivory Capital Corporation common stock for one share of Chelsea Therapeutics International, Ltd. common stock that occurred in connection with our Delaware reincorporation on July 28, 2005.

Results of Operations

The tables below set forth, for the periods indicated, certain items in our consolidated statements of income and other pertinent financial and operating data.

Comparison of Years ended December 31, 2007 and 2006

(in thousands, except percentages)	For the Year ended December 31, 2007	For the Year ended December 31, 2006	\$ Increase	% Change
Research and development expense	\$12,336	\$6,864	\$5,472	80%
Sales and marketing expense	1,294	642	652	102%
General and administrative expense	2,875	2,028	847	42%
Interest income	1,424	863	561	65%

Research and development expenses increased in 2007 primarily related to the advancement of our drug candidates into more extensive clinical testing programs and the addition of new personnel during the year and the related compensation costs. As a percentage of operating expenses, research and development costs increased to 75% for 2007 from 72% for 2006. During 2007, we continued our manufacturing, pre-clinical, Phase I and Phase II activities for CH-1504 and initiated manufacturing, formulation, pre-clinical, Phase II and Phase III activities for droxidopa. We also continued our pre-clinical activities for the portfolio of therapeutics in partnership with Active Biotech. Also contributing to the increase in research and development costs were a \$0.4 million increase in compensation and related expenses, a \$0.2 million increase in general contractor and outside services expense and an expense of approximately \$0.4 million related to warrants for 250,000 shares of our common stock, dated May 2006, the vesting of which was conditioned on an event that occurred in January 2007.

Droxidopa. Through December 31, 2007, we had spent approximately \$9.1 million in research and development expenses on droxidopa. Assuming we do not enter into an out-license, development or other collaborative agreement with respect to this compound, we estimate that subsequent to that date we will need to incur approximately \$24 million more, primarily to complete our Phase III clinical trials and submit an NDA to the FDA, to complete development of droxidopa. Assuming its approval for marketing, we currently estimate launch of this product and initial sales or royalty revenue from it no sooner than 2010. In addition to the spending requirements above, we plan to spend approximately \$9 million in 2008 for clinical proof of concept studies in other indications, our once-daily formulation and other droxidopa related programs.

Antifolates. Through December 31, 2007, we had spent approximately \$13.1 million in research and development expenses on CH-1504 and other antifolates. We currently intend to seek a partner to assist us in the development of this compound after the completion of Phase II proof-of-concept studies for rheumatoid arthritis. We estimate that, extending into early 2009, we will need to incur approximately

\$12 million more for the trials related to proof-of-concept and the development of other antifolate compounds. Assuming CH-1504 is approved for marketing, we currently estimate launch of this product and initial royalty revenue from it no sooner than 2012.

I-3D Portfolio. Through December 31, 2007, we had spent approximately \$2.5 million in research and development expenses on the I-3D portfolio of compounds we are co-developing with Active Biotech. We are conducting compound discovery work on the portfolio to try and indentify one or more lead compounds, and therefore have yet to estimate the amount of expenses it would take to move beyond this discovery stage to potential revenue generation. For 2008, Chelsea's portion of additional discovery costs are not expected to exceed \$1.0 million.

Sales and marketing expenses. We had no formalized selling activities for the year ended December 31, 2007. The increase is primarily related to a \$0.4 million increase in costs for promotional and market research related to droxidopa and its potential indications, a \$0.3 million increase in compensation and related expenses related to the hiring of our Vice President of Sales and Marketing and increases in non-cash stock-based compensation.

General and administrative expenses. The \$0.8 million increase in general and administrative expenses consists of a \$0.2 million increase in compensation and related expenses reflecting full year compensation for employees hired during 2006; a \$0.4 million increase in non-cash stock-based compensation based on grants made in February 2007, the fair values of which reflect our increased stock price and volatility; and a \$0.2 million increase in professional and consulting fees mainly related to our implementation of and compliance with Rule 404 of the Sarbanes-Oxley Act.

Interest income. During 2007, we raised approximately \$57.2 million, net of expenses, through the sale of our common stock in two financing transactions. As such, our cash and short-term investments at December 31, 2007 of approximately \$62.7 million reflects our cash and short term investments at December 31, 2006 and the infusion of capital from these financing transactions offset by approximately \$10.7 million used to fund operating activities during the year. Accordingly, interest earned on cash and short-term investments increased by \$0.6 million to \$1.4 million for 2007.

Comparison of Years Ended December 31, 2006 and 2005

(in thousands, except percentages)	For the Year ended December 31, 2006	For the Year ended December 31, 2005	\$ Increase (Decrease)	% Change
Research and development expense	\$6,864	\$5,516	\$1,348	24%
Sales and marketing expense	642	525	117	22%
General and administrative expense	2,028	2,076	(48)	-2%
Interest income	863	200	663	332%

Research and development expenses, as a percentage of operating expenses, increased to 72% for 2006 from 68% for 2005. During 2006, we incurred expenses of approximately \$3.1 million related to our licensing, manufacturing, pre-clinical, Phase I and Phase II activities for CH-1504 and other antifolates. We also incurred expenses of approximately \$2.0 million for initial licensing costs, manufacturing and formulation activities for droxidopa. In addition, we initiated work on a portfolio of therapeutics in a co-development partnership with Active Biotech and incurred expenses of approximately \$1.7 million, mainly for pre-clinical activities. Included in these expenditures are increases of \$0.1 million in compensation and related expenses, \$0.2 million in general contractor and outside services expense and \$0.1 million in travel costs.

Sales and marketing expenses. Although we had no formalized selling activities for the years ended December 31, 2006 or 2005, we did incur expenses totaling approximately \$0.6 million and \$0.5 million,

respectively. These expenses were primarily for business development activities and, during 2006, expenses incurred in the initiation and development of marketing and branding programs for droxidopa.

General and administrative expenses decreased slightly when comparing the year ended December 31, 2006 to 2005. Contributing to the decrease in these costs were a \$0.1 million decrease in investor relations expenses, primarily related to the hiring of a former third-party contractor, a \$0.1 million decrease in accounting fees and a \$0.1 million decrease in legal fees, offset by a \$0.2 million increase in compensation and related expenses and a \$0.1 million increase in travel costs.

Interest income. During 2006, we raised approximately \$19.9 million, net of expenses, through the sale of our common stock in a financing transaction. As such, our cash and short term investments at December 31, 2006 of approximately \$15.9 million reflects our cash balance at December 31, 2005 and the infusion of capital from this financing transaction offset by approximately \$7.1 million used to fund operating activities during the year. Accordingly, interest earned on cash and short-term investments increased by \$0.7 million to \$0.9 million for 2006.

Liquidity and Capital Resources

From inception to December 31, 2007, we have incurred an aggregate net loss of approximately \$34.7 million as a result of expenses similar in nature to those described above.

As of December 31, 2007, we had working capital of approximately \$57.9 million, cash and cash equivalents of approximately \$34.1 million and short-term investments of approximately \$28.6 million. We have financed our operations primarily through sales of our stock and, to a much lesser extent, through the issuance of our common stock pursuant to option or warrant exercises. Cash on hand results primarily from previous financing activities offset by funds utilized for operating and investing activities. Our financing activities are more fully described in "Financings" below.

At December 31, 2007, our short-term investments of \$28.6 million consisted of principal invested in certain auction rate securities (ARS). The ARS held by us are private placement securities with long-term nominal maturities for which the interest rates are reset through a dutch auction on 28 or 35 day cycles. The monthly auctions have historically provided a liquid market for these securities and our investments in these securities represent interests in collateralized debt obligations supported by pools of structured credit instruments consisting of student loans. None of the collateral for the ARS held by us includes mortgage, credit card or insurance securitizations. As of February 15, 2008, our ARS holdings had been reduced to \$26.5 million and all but approximately \$3.6 million were AAA/Aaa rated and insured by the Federal Family Education Loan Program (FFELP) and/or over-collateralized by more than 10%. Of the remaining \$3.6 million, all were collateralized at 100% and, consistent with our investment policy, \$750,000 carried an A rating with the remainder carrying AAA/Aaa ratings.

All ARS held at December 31, 2007 have since been successfully settled through the dutch auction process in which we, along with other investors, had the ability to liquidate positions. However since early February of 2008 we have experienced difficulty in liquidating certain of these securities as the amount of securities submitted for auction has exceeded the market demand. When the auctions for these securities fail, the investments are not readily convertible into cash until a future auction is successful, secondary markets emerges, the securities are redeemed by the issuer or they mature. Although we are experiencing a lack of liquidity for these securities at the present time, we anticipate, based on discussions with our investment advisors, that liquidity for these securities might be realized through the emergence of secondary markets, particularly considering the high default interest rates, high credit ratings, the backing of the FFELP and/or the collateralization related to the underlying securities. If liquidity is not reestablished in the short term, we may be required to reclassify these investments as long-term assets based on the nominal maturity date of the underlying securities. In addition, the value of such investments could potentially be impaired on a temporary or other-than-

temporary basis. If it is determined that the value of the investment is impaired on an other-than-temporary basis, we would be required to write down the investment to its fair value and record a charge to operations for the amount of the impairment. As liquidity returns to the market, we anticipate liquidating the majority, if not all, of these securities back into cash or cash equivalents. We do not anticipate that the temporary liquidity issues in the market for ARS will have a material impact on our liquidity or financial flexibility.

We have incurred negative cash flows from operations since inception. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and our continuing efforts to secure in-licensing opportunities. Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing or strategic alliances. Such additional funds might not become available on acceptable terms, or at all, and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. From inception through December 31, 2007 we had losses of \$34.7 million, and we anticipate losses in the range of \$38 to \$60 million during the 12 to 18 months commencing January 2008.

Actual losses will depend on a number of considerations including:

- the pace and success of pre-clinical development and clinical trials for droxidopa, antifolates and other product candidates;
- seeking regulatory approval for our various product candidates;
- discussions with regulatory agencies concerning the design of our clinical trials
- our ability to identify and recruit patients into our clinical trials at costs consistent with our current estimates;
- the pace of development of new intellectual property for our existing product candidates;
- possible out-licensing of our product candidates;
- in-licensing and development of additional product candidates;
- implementing additional internal systems and infrastructure; and
- hiring additional personnel.

Financings

On November 8, 2007, we raised gross proceeds of approximately \$48.9 million through the sale of 7,388,172 shares of our \$0.0001 par value common stock in a registered direct offering. These shares were offered pursuant to our shelf registration statement as filed with the Securities and Exchange Commission under which we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of \$60.0 million. Such registration statement became effective as of October 11, 2007. In connection with this offering, we paid commissions and recorded or accrued other offering-related expenses of approximately \$3.2 million.

On March 22, 2007, we raised gross proceeds of approximately \$12.5 million through the sale of 2,648,306 shares of our common stock plus warrants for the purchase of 794,492 shares of our common stock. The aggregate fair value of these warrants was approximately \$1.3 million. The warrants permit the holders to purchase the underlying common shares at \$5.66 each and are exercisable in whole at any time, or in part from time to time, for cash, for five years from the date of issuance. The warrants are redeemable at par value at our option in the event that the volume weighted-average closing price of our common stock is greater than \$12.00 per share for any twenty (20) consecutive trading days provided we give sixty (60) business days' written notice

to the holders and simultaneously call all warrants on the same terms. Under the terms of the placement, we agreed to and filed a registration statement with the SEC within 30 days of the closing for the shares of common stock sold and the shares of common stock underlying the warrants and such registration became effective on August 7, 2007. In connection with this offering, we paid commissions and other offering-related expenses of approximately \$1.0 million in cash.

On February 13, 2006, we raised gross proceeds of approximately \$21.5 million through the sale of 7,166,666 shares of our common stock plus warrants for the purchase of 2,149,999 shares of our common stock. The aggregate fair value of these warrants was approximately \$1.1 million. The warrants permit the holders to purchase the underlying common shares at \$4.20 each and are redeemable at our option in the event that the volume weighted average closing bid price of our common stock for any twenty (20) consecutive trading days is at least \$9.00 per share. In connection with this offering, we paid commissions and other offering-related expenses of approximately \$1.6 million in cash and issued warrants to the placement agent for the purchase of 716,666 shares of our common stock with an exercise price of \$3.30 per share, or 110% of the price of the shares sold in the offering and an aggregate fair value of approximately \$0.7 million. Under the terms of the financing we filed a registration statement with the SEC within 30 days of the closing for the shares of common stock sold and the shares of common stock underlying the warrants and such registration became effective on March 29, 2006.

In December 2004, we raised gross proceeds of approximately \$14.5 million through the sale of 5,532,994 shares of our common stock. The amount raised included the conversion of a \$1.7 million stockholder loan along with accrued interest, for which a total of 677,919 shares of common stock were issued. In connection with this offering, we paid commissions and other offering-related expenses of approximately \$1.0 million in cash and issued warrants to the placement agent for the purchase of 483,701 shares of our common stock with an aggregate fair value of approximately \$14,000.

License Agreement and Development Agreement Obligations

In March 2004, we entered into a License Agreement with Dr. M. Gopal Nair, Ph.D., of the University of South Alabama College of Medicine, for rights to use, produce, distribute and market products derived from an invention by Dr. Nair, claimed in US Patent # 5,912,251, entitled "metabolically inert anti-inflammatory and antitumor antifolates", designated by us as CH-1504 and related compounds. The license provides us exclusive, worldwide (excluding India) rights for these compounds.

In 2004, as consideration for these rights, we paid \$150,000 and issued Dr. Nair and his designees 471,816 shares of common stock at an estimated aggregate value of \$402. As additional consideration, we agreed to pay to Dr. Nair and or his designees (1) royalties on the sales should any compounds be approved for commercial sale; (2) milestone payments, payable upon achievement of clinical milestones; and (3) payments to be made on specified anniversary dates, some of which may be payable in equity, at our discretion, through 2009. We made milestone payments as required by the agreement of \$100,000 each in March 2006 and 2005. In April 2007, we issued 26,643 shares of our common stock, subject to trading restrictions, at a value of approximately \$5.63 per share, in settlement of the \$150,000 annual milestone payment for 2007. At December 31, 2007, remaining future milestone and anniversary payments, which are subject to our rights to terminate the license agreement, totaled approximately \$1,750,000. Subsequent to December 31, 2007, in January 2008, we recorded a liability for an additional milestone payment of \$100,000 related to the dosing of patients in a Phase II study that occurred during that month.

The license agreement includes certain other covenants, which require us to, among other things, maintain and prosecute patents related to the license; use commercially reasonable best efforts to bring the licensed product to market as soon as reasonably practicable and continue active, diligent marketing efforts; and prepare and provide to the licensors certain reports concerning our development and commercialization efforts. In the event we fail to carry out our responsibilities under the license agreement, the licensors may terminate the

license. We may elect to abandon the maintenance and prosecution of any patent applications or issued patents and we retain the right to terminate the license agreement in whole or as to any portion by providing written notice of such intentions to the licensor. The license agreement may also be terminated in the event we fail to make a scheduled milestone or royalty payment, we otherwise materially breach the license agreement, or if we become involved in a bankruptcy, insolvency or similar proceeding, provided that we are entitled to notice of such intention to terminate and an opportunity to cure. Regardless, the license agreement shall expire concurrent with the date of the last to expire claim contained in the patent rights.

In May 2006, we entered into an agreement with Dainippon Sumitomo Pharma Co., Ltd. (DSP) for a worldwide, exclusive, sub-licensable license and rights to certain intellectual property and proprietary information relating to droxidopa including, but not limited to all information, formulations, materials, data, drawings, sketches, designs, testing and test results, records and regulatory documentation. As consideration for these rights, we paid DSP \$100,000 and issued 63,131 shares of our common stock, with a value of approximately \$4.35 per share, or \$274,621. As additional consideration, we agreed to pay DSP and or its designees (1) royalties on the sales should any compound be approved for commercial sale; and (2) milestone payments, payable upon achievement of milestones as defined in the agreement. In January 2007, we received notification that the FDA had granted orphan drug designation for droxidopa for the treatment of symptomatic neurogenic orthostatic hypotension. Based on the terms of the DSP agreement, the granting of orphan drug designation for droxidopa triggered a milestone payment to DSP of \$250,000. We made such payment in February 2007. At December 31, 2007, remaining potential future milestone payments, subject to our right to terminate the license agreement, totaled \$3.75 million. In February 2008, we initiated patient dosing in a Phase III clinical study for droxidopa. The initiation of dosing triggered an additional milestone payment liability to DSP of \$500,000. Such payment was made in February 2008.

Subsequent to execution of the agreement, we agreed that DSP will initiate, and we will fund, activities focused on modifying the manufacturing capabilities of DSP in order to expand capacity and comply with cGMP regulations and all existing manufacturing requirements of the FDA. Such activities are currently ongoing and shall continue into 2009.

In May 2006, we entered into a development and commercialization agreement with Active Biotech AB to co-develop and commercialize the I-3D portfolio of orally active, dihydroorotate dehydrogenase (DHODH) inhibiting compounds for the treatment of autoimmune diseases and transplant rejection. Under the terms of the license and co-development agreement, an initial payment of \$1.0 million was made to Active Biotech during 2006 with such funds utilized to cover the initial costs of research and development efforts jointly approved by both parties. At December 31, 2006 we had expensed the entire \$1.0 million payment. At December 31, 2007 we had expensed cumulative costs of \$1.0 million under the program, in excess of the initial payment of \$1.0 million, related to costs of research and development. Subsequent pre-clinical and clinical development efforts will be jointly conducted and funded by both parties via a Joint Development Committee with equal representation from both parties. The agreement also provides us with the exclusive North and South American commercial rights to all drugs within this portfolio, while Active Biotech will retain rights for the remaining global markets. In addition to sharing development costs, both parties will pay royalty payments to the other on sales in their respective markets. Active Biotech will also receive certain defined milestone payments related to clinical development and receipt of revenue from commercialization of the compounds. Unless terminated by either party with six months written notice, the agreement shall remain in effect until the earlier of (1) the expiration of the last to expire patent rights indicated under the agreement or (2) fifteen (15) years from the date of the first commercial sale of the product. As of December 31, 2007, remaining potential future milestone payments, subject to our right to terminate the agreement, totaled \$15.5 million.

Current and Future Financing Needs

We have incurred negative cash flow from operations since inception. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our

planned product development efforts, our clinical trials, our research and discovery efforts and our marketing and branding initiatives. Based on our resources at December 31, 2007 and our projection of spending needs during 2008, we believe that we have sufficient capital resources to meet our operating needs into early 2009.

However, the actual amount of funds we will need to operate is subject to many factors, some of which might be beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- opportunities to sub-license our existing compounds to others;
- potential acquisitions of other compounds or companies;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

We have based our estimate on assumptions that might prove to be incorrect. Potential sources of financing include strategic relationships, public or private sales of equity or debt, the exercise of warrants by our warrant holders and other sources. We might seek to access the public or private equity markets when and if conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we might be unable to carry out our business plan. As a result, we might have to significantly delay certain activities or limit our operations and our business, financial condition and results of operations would be materially harmed.

Off-Balance Sheet Arrangements

We do not have any unconsolidated entities, and accordingly, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

Contractual Obligations and Commitments

As of December 31, 2007, we have known contractual obligations and commitments of approximately \$16.5 million, primarily related to contracted research and development activities. To facilitate an understanding of our contractual obligations and commercial commitments, the following data is provided as of December 31, 2007:

Category	Payments due by period				
	Total	< 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	\$ 29,406	\$ 29,406	\$ —	\$ —	\$—
Purchase obligations	16,490,698	13,776,946	2,301,696	412,056	—
Total	<u>\$16,520,104</u>	<u>\$13,806,352</u>	<u>\$2,301,696</u>	<u>\$412,056</u>	<u>\$—</u>

In addition, we have entered into certain other agreements that, as of December 31, 2007, might require we make contingent milestone payments of up to approximately \$21.2 million over the life of the agreements upon the achievement of certain clinical or commercial milestones. Such future payments are subject to our right to terminate the agreements. In the event that the milestones are not achieved, we elect not to pursue further testing of the drug candidate or we terminate such agreements, we will have no further obligations under the agreements. The uncertainty relating to the timing and occurrence of the commitments described prevents us from including them in the table above.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. Our significant accounting policies are more fully described in Note 1 to the consolidated financial statements accompanying this Annual Report on Form 10-K. The following accounting policies are critical in fully understanding and evaluating our reported financial results.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates and judgments. Management bases estimates on historical experience and on various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results might differ from these estimates under different assumptions or conditions.

Research and Development

Research and development expenditures are expensed as incurred. We often contract with third parties to facilitate, coordinate and perform agreed upon research and development activities. To ensure that research and development costs are expensed as incurred, we measure expense based on work performed for the underlying contract, typically utilizing a percentage-of-completion approach, and record prepaid assets or accrue expenses on a monthly basis for such activities based on the measurement of liability from expense recognition and the receipt of invoices.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. In the event that we prepay fees for future milestones, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of

time the contracted research and development services are performed. Most fees are incurred throughout the contract period and are expensed based on their percentage of completion at a particular date.

These contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs including shipping and printing fees. Because these fees are incurred at various times during the contract term and they are used throughout the contract term, we record a monthly expense allocation to recognize the fees during the contract period. Fees incurred to set up the clinical trial are expensed during the setup period.

Costs related to the acquisition of technology rights and patents for which development work is still in process are expensed as incurred and considered a component of research and development costs.

Accounting for Stock-Based Compensation

We account for our employee stock options and warrants using the fair value method as prescribed in Statement of Financial Accounting Standards No. 123R ("SFAS 123R"), *Share-based Payment*. SFAS 123R defines a fair value based method of accounting for employee stock options or similar equity instruments. In determining the fair value of the equity instrument, we considered, among other factors, (i) the risk-free interest rate, (ii) the expected life of the options granted, (iii) the anticipated dividend yield, (iv) the estimated future volatility of the underlying equity and (v) anticipated future forfeitures. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards. We estimated the expected life of the options granted based on anticipated exercises in future periods assuming the success of our business model as currently forecasted. The expected dividends reflect our current and expected future policy for dividends on our common stock. To determine the expected stock price volatility for our stock options, we examined historical volatilities for industry peers as we do not have sufficient trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumption as more historical data for our common stock becomes available. Given the limited service period for our current employees and the senior nature of the roles for those employees, we estimated that we would experience no forfeitures for those options currently outstanding. Our results include non-cash compensation expense as a result of the issuance of stock option grants utilizing this method. We expect to record additional non-cash compensation expense in the future, which might be significant, particularly if our stock price increases. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our cash in a variety of financial instruments in order to preserve principal and liquidity while maximizing returns and we do not invest in financial instruments or their derivatives for trading or speculative purposes. To minimize the exposure due to adverse shifts in interest rates, we maintain investments of shorter maturities. Our investment guidelines include security type, credit quality and maturity and are intended to limit market risk by restricting our investments to high quality debt instruments with relatively short maturities. At December 31, 2007, our investments primarily consisted of money market funds, corporate debt securities and commercial paper with an average maturity under 90 days and auction rate securities (ARS) with long-term nominal maturities for which the interest rates are reset through a dutch auction each month. All investments to date have been made in U. S. dollars and accordingly, we do not have any exposure to foreign currency rate fluctuations.

Our interest income is sensitive to changes in the general level of interest rates in the United States, particularly since our investments are and will be in short-term investments. To assess our interest rate risk, we performed a sensitivity analysis projecting potential future interest earnings on investments in which we estimated the impact of a 1%, or 100 basis point, increase or decrease in our average interest rate over a 12 month time horizon. This analysis resulted in a potential effect of approximately \$400,000 on the interest earned on investments.

At December 31, 2007, we had \$28.6 million of principal invested in auction rate securities (ARS). As of February 15, 2008, we had reduced our holdings in ARS investments to approximately \$26.5M. The monthly auctions for these ARS investments have historically provided a liquid market for these securities. Our investments in ARS represent interests in collateralized debt obligations supported by pools of student loans, typically over-collateralized and/or insured by the Federal Family Education Loan Program (FFELP). None of the ARS investments in our portfolio were backed by sub-prime mortgage loans or other collateral with exposure to certain current market conditions. Additionally, all ARS holdings at December 31, 2007 have subsequently been successfully settled through the dutch auction process either being liquidated into cash or experiencing an interest rate reset.

However, liquidity issues experienced recently in global credit and capital markets have prevented us from liquidating certain ARS investments that reset subsequent to December 31, 2007 as the amount of securities submitted for sale at recent ARS auctions has exceeded the market demand, though they continue to pay interest according to their stated terms. Although insufficient demand for certain ARS may continue, we anticipate, based on discussions with our investment advisors, that liquidity for our securities may possibly be realized through the emergence of secondary markets in the near term, particularly considering the high default interest rates, high credit ratings, the backing of the FFELP and/or the underlying assets collateralizing these investments. As such, we believe that the primary impact of the failed auctions is reduced liquidity rather than impairment of principal. In the event that we are unable to sell the investments at or above our carrying value, these securities may not provide us a liquid source of cash.

Notwithstanding the above, if uncertainties in the credit and capital markets continue and secondary markets for ARS do not emerge, we may not be able to convert these investments into cash during our required timeframe. Even if secondary markets do emerge, we may experience a temporary loss of principal if such securities are initially marketed at a discount or a sustained loss if it becomes necessary to sell these investments at such a discount. In addition, should the credit ratings of our ARS be downgraded, we might incur further problems in liquidating our investments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

(a) The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of the financial statements filed herewith is found on page 49.

(b) The unaudited quarterly financial data for the two-year period ended December 31, 2007 is as follows:

	Year ended December 31, 2006			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Operating expenses	\$ 2,441,780	\$ 2,091,556	\$ 2,353,937	\$ 2,646,911
Loss from operations	(2,441,780)	(2,091,556)	(2,353,937)	(2,646,911)
Net loss	(2,295,959)	(1,843,926)	(2,110,788)	(2,420,703)
Basic and diluted loss per share (a)	\$ (0.14)	\$ (0.09)	\$ (0.11)	\$ (0.12)
	Year ended December 31, 2007			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Operating expenses	\$ 4,033,316	\$ 3,481,046	\$ 3,550,306	\$ 5,440,719
Loss from operations	(4,033,316)	(3,481,046)	(3,550,306)	(5,440,719)
Net loss	(3,835,880)	(3,163,427)	(3,242,816)	(4,839,422)
Basic and diluted loss per share (a)	\$ (0.19)	\$ (0.14)	\$ (0.14)	\$ (0.18)

(a) Basic and diluted loss per common share for each of the quarters presented above is based on the respective weighted average number of common shares for the quarters. As such, the sum of the quarters may not

necessarily be equal to the full year loss per share amount. Basic and diluted loss per share are identical since potentially dilutive securities are excluded from the calculations, as the effect would be anti-dilutive for all periods presented.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that they will meet their objectives that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e)) pursuant to Exchange Act Rule 13a-15. Based upon that evaluation and subject to the foregoing, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2007.

Changes in internal control over financial reporting.

Management has determined that, as of December 31, 2007, there were no changes in our internal control over financial reporting that occurred during our fiscal quarter then ended that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, management used the criteria set forth by the Committee of the Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework and the Guidance for Smaller Public Companies as published by COSO in June 2006. Based on our assessment, management believes that we maintained effective internal control over financial reporting as of December 31, 2007, based on those criteria.

J.H. Cohn LLP, our independent registered public accounting firm, which has audited the financial statements included in Part IV, Item 15 of this report, has also audited our internal control over financial reporting as of December 31, 2007, as stated in their report, which is included below.

Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

The Board of Directors and Stockholders
Chelsea Therapeutics International, Ltd.

We have audited Chelsea Therapeutics International, Ltd. and Subsidiary's (A Development State Company) internal control over financial reporting as of December 31, 2007, based on criteria established in "Internal Control-Integrated Framework" issued by the Committee of the Sponsoring Organizations of the Treadway Commission. Chelsea Therapeutics International, Ltd. and Subsidiary's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Chelsea Therapeutics International, Ltd. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007 based on criteria established in "Internal Control-Integrated Framework" issued by the Committee of the Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Chelsea Therapeutics International, Ltd. and Subsidiary as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 and for the period from April 3, 2002 (inception) to December 31, 2007 and our report dated March 10, 2008 expressed an unqualified opinion.

/s/ J. H. COHN LLP
March 10, 2008

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Incorporated by reference from the information in our proxy statement for the 2008 Annual Meeting of Stockholders, which we will file with the Securities and Exchange Commission within 120 days of the end of the fiscal year to which this report relates.

The information required by Item 10 with respect to identification of our executive officers has been included in Item 1 of this Form 10-K in reliance on General Instruction G of Form 10-K and Instruction 3 to Item 401(b) of Regulation S-K.

ITEM 11. EXECUTIVE COMPENSATION

Incorporated by reference from the information in our proxy statement for the 2008 Annual Meeting of Stockholders, which we will file with the Securities and Exchange Commission within 120 days of the end of the fiscal year to which this report relates.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Incorporated by reference from the information in our proxy statement for the 2008 Annual Meeting of Stockholders, which we will file with the Securities and Exchange Commission within 120 days of the end of the fiscal year to which this report relates.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Incorporated by reference from the information in our proxy statement for the 2008 Annual Meeting of Stockholders, which we will file with the Securities and Exchange Commission within 120 days of the end of the fiscal year to which this report relates.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Incorporated by reference from the information in our proxy statement for the 2008 Annual Meeting of Stockholders, which we will file with the Securities and Exchange Commission within 120 days of the end of the fiscal year to which this report relates.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a) Financial Statements.

The following statements are filed as part of this report:

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Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statements of Stockholders' Equity	F-4
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Notes to Consolidated Financial Statements	F-8

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(b) Exhibits.

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
2.1	Agreement and Plan of Merger by and among Ivory Capital Corporation, Chelsea Therapeutics, Inc. and Chelsea Acquisition Corp, dated as of January 17, 2005.	8-K	01/17/05	2.1	
2.2	Agreement and Plan of Merger between Ivory Capital Corporation and Chelsea Therapeutics International, Ltd., dated as of June 17, 2005.	8-K	07/28/05	2.2	
3.1	Certificate of Incorporation for Chelsea Therapeutics International, Ltd.	S-1/A	08/18/05	3.1	
3.2	Bylaws of Chelsea Therapeutics International, Ltd.	S-1/A	08/18/05	3.2	
10.1*	License Agreement dated as of March 24, 2004 between M. Gopal Nair and Chelsea Therapeutics, Inc. (f/k/a Aspen Therapeutics, Inc.)	8-K	02/16/05	10.1	
10.3	Form of Subscription Agreement for the purchase of Series A Preferred Stock of Chelsea Therapeutics, Inc.	8-K	02/16/05	10.3	
10.4	Chelsea Therapeutics, Inc. 2004 Stock Plan, as amended, and forms of Notice of Stock Option Grant and Stock Option Agreement, as amended.	10-K	03/12/07	10.4	
10.5	Form of Subscription Agreement and Warrant for the purchase of common stock, par value \$0.0001 per share, of Chelsea Therapeutics International, Ltd.	8-K	02/17/06	10.5	
10.6	Placement Agency Agreement dated November 28, 2005 between Chelsea Therapeutics International, Ltd. and Paramount BioCapital, Inc.	10-K	03/08/06	10.6	
10.7	Employment Agreement between Chelsea Therapeutics International, Ltd. and Dr. Simon Pedder, effective May 1, 2006.	8-K	05/01/06	10.7	
10.8*	Development and Commercialization Agreement dated as of May 5, 2006 between Active Biotech AB and Chelsea Therapeutics International, Ltd.	10-Q	08/14/06	10.8	
10.9*	Exclusive License Agreement dated May 26, 2006 between Dainippon Sumitomo Pharma Co., Ltd. and Chelsea Therapeutics, Inc.	10-Q	08/14/06	10.9	
10.10*	Finder's Agreement dated May 26, 2006 between Paramount BioCapital, Inc. and Chelsea Therapeutics International, Ltd.	10-Q	08/14/06	10.10	
10.11	Form of Subscription Agreement for the purchase of common stock of Chelsea Therapeutics International, Ltd. dated March 19, 2007 and related form of Warrant, dated March 22, 2007.	8-K	03/20/07	10.11	
10.12	Form of Subscription Agreement for the purchase of common stock of Chelsea Therapeutics International, Ltd. dated November 1, 2007.	8-K	11/02/07	10.12	

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
21.1	Subsidiaries of Chelsea Therapeutics International, Ltd.	10-K	03/12/07	10.4	
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification by the Chief Executive Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
31.2	Certification by the Chief Financial Officer pursuant to Section 240.13a-14 or section 240.15d-14 of the Securities and Exchange Act of 1934, as amended.				X
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

* The registrant received confidential treatment with respect to certain portions of this exhibit. Such portions have been omitted from this exhibit and have been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 11th day of March 2008.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD.

By: /s/ SIMON PEDDER
Simon Pedder, Ph.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the 11th day of March 2008.

<u>Name</u>	<u>Title</u>
<u>/s/ SIMON PEDDER</u> Simon Pedder, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ J. NICK RIEHLE</u> J. Nick Riehle	Vice President, Administration and Chief Financial Officer (Principal Financial and Accounting Officer)
<u>/s/ MICHAEL WEISER</u> Michael Weiser, M.D., Ph.D.	Director
<u>/s/ KEVAN CLEMENS</u> Kevan Clemens, Ph.D.	Director
<u>/s/ NEIL HERSKOWITZ</u> Neil Herskowitz	Director
<u>/s/ JOHNSON Y. N. LAU</u> Johnson Y.N. Lau, M.D.	Director
<u>/s/ NORMAN HARDMAN</u> Norman Hardman, Ph.D.	Director
<u>/s/ ROGER STOLL</u> Roger Stoll, Ph.D.	Director

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Chelsea Therapeutics International, Ltd.

We have audited the accompanying consolidated balance sheets of Chelsea Therapeutics International, Ltd. and Subsidiary (A Development Stage Company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 and the period from April 3, 2002 (inception) to December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Chelsea Therapeutics International, Ltd. and Subsidiary (A Development Stage Company) as of December 31, 2007 and 2006, and their results of operations and cash flows for each of the three years in the period ended December 31, 2007 and the period from April 3, 2002 (inception) to December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Chelsea Therapeutics International, Ltd. and Subsidiary's internal control over financial reporting as of December 31, 2007, based on criteria established in "Internal Control-Integrated Framework" issued by the Committee of the Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2008 expressed an unqualified opinion.

/s/ J. H. COHN LLP

Roseland, New Jersey
March 10, 2008

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2007</u>	<u>December 31,</u> <u>2006</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 34,076,217	\$ 3,111,502
Short-term investments	28,638,336	12,785,827
Prepaid contract research and manufacturing	299,319	167,606
Other prepaid expenses and other current assets	93,243	49,214
Total current assets	63,107,115	16,114,149
Property and equipment, net	42,793	42,938
Other assets	13,461	13,461
	<u>\$ 63,163,369</u>	<u>\$ 16,170,548</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 888,560	\$ 41,255
Accrued compensation and related expenses	567,268	409,955
Accrued contract research and manufacturing	3,540,629	1,448,470
Other accrued expenses	200,333	134,312
Total liabilities	5,196,790	2,033,992
Commitments		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$0.0001 par value, 45,000,000 shares authorized, 29,917,454 and 19,707,129 shares issued and outstanding, respectively	2,992	1,971
Additional paid-in capital	92,648,789	33,738,242
Deficit accumulated during the development stage	(34,685,202)	(19,603,657)
Total stockholders' equity	57,966,579	14,136,556
	<u>\$ 63,163,369</u>	<u>\$ 16,170,548</u>

See accompanying notes to consolidated financial statements.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31,			Period from April 3, 2002 (inception) to December 31, 2007
	2007	2006	2005	
Operating expenses:				
Research and development	\$ 12,336,266	\$ 6,864,357	\$ 5,515,596	\$ 26,524,869
Sales and marketing	1,294,359	642,263	524,597	2,629,698
General and administrative	2,874,762	2,027,564	2,075,978	7,990,004
Total operating expenses	<u>16,505,387</u>	<u>9,534,184</u>	<u>8,116,171</u>	<u>37,144,571</u>
Operating loss	(16,505,387)	(9,534,184)	(8,116,171)	(37,144,571)
Interest income	1,423,842	862,808	200,449	2,493,389
Interest expense	—	—	—	(34,020)
Net loss	<u>\$(15,081,545)</u>	<u>\$(8,671,376)</u>	<u>\$(7,915,722)</u>	<u>\$(34,685,202)</u>
Net loss per basic and diluted share of common stock	<u>\$ (0.66)</u>	<u>\$ (0.46)</u>	<u>\$ (0.64)</u>	
Weighted average number of basic and diluted common shares outstanding	<u>22,936,780</u>	<u>18,780,638</u>	<u>12,321,061</u>	

See accompanying notes to consolidated financial statements.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

	Common stock		Additional Paid-In Capital	Unpaid Subscription on common stock	Deferred stock-based compensation	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount					
Issuance of common stock to founders in April 2002	5,428,217	\$ 542	\$ 4,083	\$(4,625)	\$ —	\$ —	\$ —
Balance at December 31, 2003	5,428,217	\$ 542	\$ 4,083	\$(4,625)	\$ —	\$ —	\$ —
Common stock issued in March 2004, at approximately \$0.0009 per share, for license fee	471,816	47	355	—	—	—	402
Sale and issuance of common stock in April 2004, at approximately \$0.0009 per share to chief executive	478,330	48	360	—	—	—	408
Receipt of cash for stock subscription receivable	—	—	—	4,625	—	—	4,625
Sale and issuance of common stock with detachable warrants in December 2004 at approximately \$2.45 per share, net of issuance costs	5,532,994	554	13,550,255	—	—	—	13,550,809
Deferred stock-based compensation	—	—	33,525	—	(33,525)	—	—
Amortization of deferred stock-based compensation	—	—	—	—	1,529	—	1,529
Net loss	—	—	—	—	—	(3,016,559)	(3,016,559)
Balance at December 31, 2004	11,911,357	\$1,191	\$13,588,578	\$ —	\$(31,996)	\$ (3,016,559)	\$10,541,214
Recapitalization of the Company (See Note 1)	457,168	46	(400,046)	—	—	—	(400,000)
Employee stock options exercised	14,663	1	998	—	—	—	999
Adoption of SFAS 123R	—	—	(31,996)	—	31,996	—	—
Amortization of deferred stock-based compensation	—	—	99,319	—	—	—	99,319
Variable accounting for stock options granted to third party	—	—	58,594	—	—	—	58,594
Net loss	—	—	—	—	—	(7,915,722)	(7,915,722)
Balance at December 31, 2005	12,383,188	\$1,238	\$13,315,447	\$ —	\$ —	\$(10,932,281)	\$ 2,384,404
Sale and issuance of common stock with detachable warrants in February 2006 at approximately \$2.77 per share, net of issuance costs	7,166,666	717	19,854,935	—	—	—	19,855,652
Common stock issued in March 2006, at par, pursuant to net-share (cashless) exercise of common stock warrants	15,461	2	(2)	—	—	—	—
Common stock issued in May 2006, at approximately \$4.35 per share, for license fee	63,131	6	274,615	—	—	—	274,621
Employee stock options exercised	78,683	8	5,072	—	—	—	5,080
Stock-based compensation	—	—	283,983	—	—	—	283,983
Variable accounting for stock options granted to third party	—	—	4,192	—	—	—	4,192
Net loss	—	—	—	—	—	(8,671,376)	(8,671,376)
Balance at December 31, 2006	19,707,129	\$1,971	\$33,738,242	\$ —	\$ —	\$(19,603,657)	\$14,136,556

See accompanying notes to consolidated financial statements.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY—(Continued)

	<u>Common stock</u>		<u>Additional Paid-In Capital</u>	<u>Unpaid Subscription on common stock</u>	<u>Deferred stock-based compensation</u>	<u>Deficit accumulated during the development stage</u>	<u>Total stockholders' equity</u>
	<u>Shares</u>	<u>Amount</u>					
Balance at December 31, 2006	19,707,129	\$1,971	\$33,738,242	\$—	\$—	\$(19,603,657)	\$ 14,136,556
Common stock issued during 2007, at par, pursuant to net-share (cashless) exercises of common stock warrants ...	68,136	6	(6)	—	—	—	—
Fair value of warrants issued in May 2006 in consideration of finders fee at approximately \$1.75 per share for which vesting was conditioned on an event that occurred in January 2007	—	—	433,750	—	—	—	433,750
Sale and issuance of common stock with detachable warrants in March 2007 at approximately \$4.33 per share, net of issuance costs	2,648,306	265	11,476,412	—	—	—	11,476,677
Common stock issued in April 2007, at approximately \$5.63 per share, for license fee	26,643	3	149,997	—	—	—	150,000
Common stock issued in June 2007, at \$4.20 per share, pursuant to exercise of common stock warrants, net of fees ...	60,000	6	246,994	—	—	—	247,000
Common stock issued in October 2007, at \$4.20 per share, pursuant to exercise of common stock warrants	1,200	—	5,040	—	—	—	5,040
Sale and issuance of common stock in November 2007 at approximately \$6.19 per share, net of issuance costs	7,388,172	739	45,754,030	—	—	—	45,754,769
Employee stock options exercised	17,868	2	15,704	—	—	—	15,706
Stock-based compensation	—	—	828,626	—	—	—	828,626
Net loss	—	—	—	—	—	(15,081,545)	(15,081,545)
Balance at December 31, 2007	<u>29,917,454</u>	<u>\$2,992</u>	<u>\$92,648,789</u>	<u>\$—</u>	<u>\$—</u>	<u>\$(34,685,202)</u>	<u>\$ 57,966,579</u>

See accompanying notes to consolidated financial statements.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December 31,			Period from April 3, 2002 (inception) to December 31, 2007
	2007	2006	2005	
Operating activities:				
Net loss	\$(15,081,545)	\$ (8,671,376)	\$(7,915,722)	\$(34,685,202)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash stock-based compensation	828,626	283,983	99,319	1,213,457
Non-cash stock-based variable accounting compensation	—	4,192	58,594	62,786
Depreciation and amortization	31,022	35,389	25,527	103,309
Stock issued for license fee	150,000	274,621	—	425,023
Non-cash interest expense	—	—	—	34,020
Fair value of warrants for finder's fee	433,750	—	—	433,750
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(175,743)	(19,891)	(97,904)	(392,562)
Accounts payable, accrued contract research and manufacturing expenses and other accrued expenses	3,005,486	826,690	416,312	4,629,524
Accrued compensation and related expenses	157,313	164,682	26,733	567,268
Net cash used in operating activities	<u>(10,651,091)</u>	<u>(7,101,710)</u>	<u>(7,387,141)</u>	<u>(27,608,627)</u>
Investing activities:				
Acquisitions of property and equipment	(30,877)	(35,127)	(17,564)	(146,104)
Purchase of short-term investments, net of redemptions	(15,852,509)	(12,785,827)	—	(28,638,336)
Security deposits	—	—	—	(13,461)
Net cash used in investing activities	<u>(15,883,386)</u>	<u>(12,820,954)</u>	<u>(17,564)</u>	<u>(28,797,901)</u>
Financing activities:				
Proceeds from borrowings from affiliate	—	—	—	1,745,000
Proceeds from exercise of stock options	15,706	5,080	999	21,785
Proceeds from exercise of common stock warrants	252,040	—	—	252,040
Proceeds from sales of equity securities, net of issuance costs	57,231,446	19,855,652	—	88,859,295
Recapitalization of the Company	—	—	(400,000)	(400,000)
Receipt of cash for stock subscription receivable	—	—	—	4,625
Net cash provided by (used in) financing activities	<u>57,499,192</u>	<u>19,860,732</u>	<u>(399,001)</u>	<u>90,482,745</u>
Net increase (decrease) in cash and cash equivalents	30,964,715	(61,932)	(7,803,706)	34,076,217
Cash and cash equivalents, beginning of year	3,111,502	3,173,434	10,977,140	—
Cash and cash equivalents, end of year	<u>\$ 34,076,217</u>	<u>\$ 3,111,502</u>	<u>\$ 3,173,434</u>	<u>\$ 34,076,217</u>

See accompanying notes to consolidated financial statements.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

Supplemental disclosure of non-cash investing and financing activities:

During 2002, the Company issued 5,428,217 shares of its \$0.0001 par value common stock for a subscription receivable of \$4,625.

During 2004, the Company converted a loan with an affiliate for aggregate principal of \$1,745,000 and accrued interest of \$34,020 into shares of the Company's \$0.0001 par value common stock, issuing 677,919 shares, at approximately \$2.62 per share in lieu of repayment of this obligation.

In December 2004, in conjunction with and as compensation for activities related to the December 2004 sale of equity securities, the Company issued warrants to purchase 483,701 shares of its \$0.0001 par value common stock, with a purchase price of approximately \$2.88 per share and an aggregate fair value of \$14,400. In September 2007, February 2007 and March 2006, 8,667 shares, 4,928 shares and 15,461 shares, respectively, of the \$0.0001 par value common stock of the Company were issued to holders upon exercise of warrants issued in December 2004 per the net share settlement provisions contained in the terms of the warrants.

In conjunction with the merger and recapitalization of the Company dated February 11, 2005, the Company issued 11,911,357 shares of its \$0.0001 par value common stock in exchange for all of the issued and outstanding shares of Chelsea Therapeutics, Inc. In addition, in conjunction with and as compensation for facilitating the merger, the Company issued warrants for the purchase of 105,516 shares of its \$0.0001 par value common stock at an exercise price of \$2.62 per share and an aggregate fair value of \$26,700. In July 2007, 33,203 shares of the \$0.0001 par value common stock of the Company were issued to the holder upon exercise of warrants issued in February 2005 per the net share settlement provisions contained in the terms of the warrants.

In February 2006, in conjunction with and as compensation for activities related to the February 2006 sale of equity securities, the Company issued warrants to purchase 716,666 shares of its \$0.0001 par value common stock, with a purchase price of \$3.30 per share and an aggregate fair value of approximately \$705,000.

In May 2006, in conjunction with and as compensation for activities related to a licensing agreement and under a Finder's Agreement, the Company issued warrants to purchase 250,000 shares of its \$0.0001 par value common stock, with an exercise price of \$4.31 per share. The exercise of these warrants was conditioned on an event that occurred in January 2007 and, accordingly, the Company recorded a charge based on the warrants' fair value determined at January 2007 of \$433,750 (see Note 5).

See accompanying notes to consolidated financial statements.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. The Company, Basis of Presentation and Summary of Significant Accounting Policies

The Company

Chelsea Therapeutics International, Ltd. ("Chelsea Ltd." or the "Company") is a specialty pharmaceutical company focused on the acquisition, development and commercialization of innovative pharmaceutical products. The Company's currently licensed compounds target a variety of prevalent medical conditions; particularly rheumatoid arthritis, psoriasis, cancer, other immunological disorders, neurogenic orthostatic hypotension and other autonomic disorders. The Company's operating subsidiary, Chelsea Therapeutics, Inc. ("Chelsea Inc."), was incorporated in the State of Delaware on April 3, 2002 as Aspen Therapeutics, Inc., with the name changed in July 2004. In February 2005, Chelsea Inc. merged with a wholly-owned subsidiary of our predecessor company, Ivory Capital Corporation ("Ivory"), a Colorado public company with no operations (the "Merger"). The Company reincorporated into the State of Delaware in July 2005, changing its name to Chelsea Therapeutics International, Ltd. ("Chelsea Ltd.").

As a result of the Merger of Ivory and Chelsea Inc. in February 2005, and the reincorporation in Delaware in July 2005, Chelsea Ltd. is the reporting company and is the 100% owner of Chelsea Inc. The separate existence of Ivory ceased in connection with the Delaware reincorporation in July 2005. Except where the context provides otherwise, references to "the Company" and similar terms mean Ivory, Chelsea Ltd. and Chelsea Inc.

Basis of Presentation

Since inception, the Company has focused primarily on organizing and staffing, negotiating in-licensing agreements with partners, acquiring, developing and securing proprietary technology, participating in regulatory discussions with the FDA, the EMEA and other regulatory agencies and undertaking pre-clinical trials and clinical trials of product candidates. The Company is a development stage company and has generated no revenue since inception.

The Company has sustained operating losses since its inception and expects such losses to continue over the next several years. Management plans to continue financing the operations with equity issuances, debt arrangements, strategic alliances or other arrangements of a collaborative nature. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research or development programs, or cease operations. Based on the Company's resources at December 31, 2007 and the projection of spending needs during 2008, management believes that the Company's capital resources are sufficient to support planned operational activities into early 2009. If it is determined that additional financing is needed in the future and the Company is not able to obtain financing when needed, it might be unable to carry out its business plan. As a result, the Company might have to significantly delay certain activities or limit operations and its business, financial condition and results of operations would be materially harmed.

For presentation purposes, the Company has restated all information contained in this report related to shares authorized, issued and outstanding and related disclosures of weighted average shares and loss per share to reflect the results of the Delaware reincorporation in July 2005 as if the Delaware reincorporation had occurred at the beginning of each of the periods presented. The Company has also corrected the classification of the auction rate securities included in cash and cash equivalents at December 31, 2006 and has classified those auction rate securities as short-term investments.

Basis of Consolidation

All significant intercompany transactions and balances have been eliminated in consolidation.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates and judgments. Management bases estimates on its historical experience and on various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and other highly-liquid investments with maturities of three months or less from the date of purchase.

Short-term Investments

Short-term investments consist of investments in certain auction rate securities (ARS). ARS are generally long-term debt instruments for which interest rates are reset through a dutch auction process that occurs at pre-determined calendar intervals, generally each 28 or 35 days. The Company accounts for such investments utilizing Statement of Financial Accounting Standards No. 115 (SFAS 115), *Accounting for Certain Investments in Debt and Equity Securities*. SFAS 115 requires that the Company evaluate whether an event or change in circumstances has occurred during the period that may have a significant adverse effect on the fair value of the investment (an "impairment indicator") at the balance sheet date. If an impairment indicator is present, the Company would perform an analysis based on other-than-temporary impairment factors to determine if a decline in value had occurred and whether such decline is temporary or other-than-temporary. If it is determined that the decline in value is other-than-temporary, then an impairment loss would be recognized in operations and the remaining value of such investments, if any, would, most likely, be reclassified as long-term investments based on their maturity dates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and holds investments in commercial paper with maturities no greater than ninety (90) days. However, management believes the Company is not exposed to significant credit risk for its cash and cash equivalents due to the financial position of the depository institutions in which those deposits are held and the high credit ratings of the organizations issuing the various commercial paper investments.

The Company also holds positions in short-term investments that consist of certain ARS. These investments represent interests in collateralized debt obligations supported by pools of student loans. Consistent with Company policy, all ARS investments have at least A credit ratings at the time of purchase. Should an auction fail related to one or more of these investments, the investment may not be readily convertible to cash until a future auction is successful, secondary markets development for these securities, the security is redeemed by the issuer or the security matures. The Company would continue to receive interest according to the stated terms of the investments but would experience a loss of liquidity related to the portion of its portfolio that failed to find market support upon auction.

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Fair Value of Financial Instruments

The carrying value of the Company's financial instruments, including cash and cash equivalents, short-term investments and accounts payable approximates fair value given their highly-liquid and short-term nature.

Property and Equipment

Property, which consists of furniture and fixtures, software and equipment, is stated at cost and depreciated or amortized using the straight-line method over the estimated useful lives of the related assets. The useful life for all classes of assets is three (3) years.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. Impairment, if any, is assessed using undiscounted cash flows. Through December 31, 2007, there has been no such impairment.

Research and Development

Research and development expenditures are expensed as incurred. We often contract with third parties to facilitate, coordinate and perform agreed upon research and development activities. To ensure that research and development costs are expensed as incurred, we measure expense based on work performed for the underlying contract, typically utilizing a percentage-of-completion approach, and record prepaid assets or accrue expenses on a monthly basis for such activities based on the measurement of liability from expense recognition and the receipt of invoices.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. In the event that we prepay fees for future milestones, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most fees are incurred throughout the contract period and are expensed based on their percentage of completion at a particular date.

These contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs including shipping and printing fees. Because these fees are incurred at various times during the contract term and they are used throughout the contract term, we record a monthly expense allocation to recognize the fees during the contract period. Fees incurred to set up the clinical trial are expensed during the setup period.

Costs related to the acquisition of technology rights and patents for which development work is still in process are expensed as incurred and considered a component of research and development costs.

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Loss per Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and diluted net loss per common share are identical as potentially dilutive securities from stock options and stock warrants would have an antidilutive effect since the Company incurred a net loss. The number of shares of common stock potentially issuable at December 31, 2007, 2006 and 2005 upon exercise or conversion that were not included in the computations of net loss per share were 6,572,308, 5,307,980 and 1,641,157, respectively.

Income Taxes

In accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* (SFAS 109), a deferred tax asset or liability is determined based on the difference between the financial statement and the tax bases of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

On January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies the criteria for recognizing tax benefits related to uncertain tax positions under SFAS 109 and requires additional financial statement disclosure. FIN 48 requires that the Company recognize, in its consolidated financial statements, the impact of a tax position if that position is more likely than not to be sustained upon examination, based on the technical merits of the position. FIN 48 also requires explicit disclosure about the Company's uncertainties related to the income tax position, including a detailed roll-forward of tax benefits taken that do qualify for financial statement recognition. Adoption of FIN 48 had no impact on the Company's consolidated results of operations and financial position.

Stock-Based Compensation

The Company accounts for its stock options utilizing Statement of Financial Accounting Standards No. 123(R) ("SFAS 123R"), *Share-based Payment*. SFAS 123R requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and non-employee directors based on estimated fair values determined using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's statements of operations. Prior to the adoption of SFAS 123R on February 11, 2005, the date of the Merger (see Note 1), the Company accounted for stock options issued to employees and non-employee directors under Statement of Financial Accounting Standards No. 123 ("SFAS 123"), *Accounting for Stock-based Compensation*.

The Company adopted SFAS 123R using the modified prospective application to all grants made after February 11, 2005. The adoption of SFAS 123R had no effect on the financial results of the Company from the application of the original provisions of SFAS 123.

The fair value of each option award made to employees and directors during the years ended December 31, 2007, 2006 and 2005 was estimated on the date of grant using the Black-Scholes closed-form option valuation model utilizing the assumptions noted in the following table. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company estimated the expected life of the options granted based on anticipated exercises in future periods assuming the success of its business model as currently forecasted. The

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expected dividends reflect the Company's current and expected future policy for dividends on its common stock. To determine the expected stock price volatility for the Company's stock options, the Company examined historical volatilities for industry peers as the Company does not have sufficient trading history for its common stock. The Company will continue to analyze the expected stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. Given the limited service period for its current employees and the senior nature of the roles for those employees, the Company estimated that it would experience no forfeitures for those options outstanding as of December 31, 2007. Prior to February 11, 2005, under the provisions of SFAS 123, the Company utilized the minimum value method and assumed no volatility in determining the fair value of options granted. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

	For the years ended December 31,		
	2007	2006	2005
Risk-free interest rate	4.24% to 4.95%	4.31% to 5.12%	3.72% to 3.89%
Expected life of options	5 years	5 years	5 years
Expected dividend yield	0%	0%	0%
Expected volatility	66.01%	37.66%	0% to 41.31%
Forfeitures	0%	0%	0%

The Company recorded compensation expense of \$828,626, \$283,983 and \$99,319 for the years ended December 31, 2007, 2006 and 2005, respectively, in conjunction with option grants made to employees and non-employee directors. As of December 31, 2007, the Company had total unrecognized compensation expense related to options granted to employees and non-employee directors of approximately \$2.4 million, which will be recognized over a remaining average period of 2.7 years. The expected future amortization expense for unrecognized compensation expense for stock option grants to employees and non-employee directors at December 31, 2007 is as follows:

Year ending December 31, 2008	\$ 895,072
Year ending December 31, 2009	812,075
Year ending December 31, 2010	614,056
Year ending December 31, 2011	66,443
	<u>\$2,387,646</u>

Options granted to consultants, advisors or other independent contractors that provide services to the Company are accounted for under the provisions of SFAS 123R and Emerging Issues Task Force Issue No. 96-18 ("EITF 96-18"), *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. To date, option awards to consultants, advisors or other independent contractors have been granted with an exercise price equal to the market price of the Company's stock at the date of the grant; have 10-year contractual terms; and vest dependent upon the completion of performance commitments. As such, the value of stock options is measured at the then-current market value as of financial reporting dates and compensation cost is recognized for the net change in the fair value of the options for the reporting period, until such performance commitments are met. Once each commitment is met, the options that vest in association with that commitment are adjusted, for the last-time, to the then-current fair value and compensation cost is recognized accordingly (See Note 5).

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In determining the fair value of options granted to consultants, advisors and other independent contractors, the Company uses the Black-Scholes closed-form option valuation model in a manner consistent with its use in determining the fair value of options granted to employees and directors. However, the expected life of the options is based on the contractual lives as defined in agreements with the third parties and ranged from one to three years for grants made during 2005. No such grants were made during 2006 or 2007.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement No. 157, "*Fair Value Measurements*" (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities and requires additional disclosure about the use of fair value measures, the information used to measure fair value and the effect fair value measurements have on earnings. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and will be effective for the Company on January 1, 2008. The Company currently believes that the adoption of SFAS 157 will have no material impact on its consolidated financial position or results of operations.

In February 2007, FASB issued Statement No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No 115*" (SFAS 159). SFAS 159 provides an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and will be effective for the Company on January 1, 2008. The Company currently believes that the adoption of SFAS 159 will have no material impact on its consolidated financial position or results of operations.

In December 2007, FASB affirmed the conclusions of the Emerging Issues Task Force (EITF) on EITF Issue 07-1, "*Accounting for Collaborative Arrangements*" (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities, for which they act as the principal, on a gross basis and report any payments received from or made to other collaborators based on other applicable accounting principles generally accepted in the United States (GAAP) or, in the absence of GAAP, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer relationship subject to EITF 01-9 "*Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*". EITF 07-1 is effective for fiscal years beginning after December 15, 2008 and will be effective for the Company on January 1, 2009. The Company currently believes that the adoption of EITF 07-1 will have no material impact on its consolidated financial position or results of operations.

In June 2007, the FASB affirmed the conclusions of the EITF with respect to EITF Issue 07-3 "*Accounting for Advance Payments for Goods or Services to be Used in Future Research and Development Activities*" (EITF 07-3). EITF 07-3 concluded that non-refundable advance payments for future research and development activities pursuant to an executory contractual arrangement should be capitalized until the goods have been delivered or the related services performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2008 and will be effective for the Company on January 1, 2009. The Company currently believes that the adoption of EITF 07-3 will have no material impact on its consolidated financial position or results of operations.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

2. Balance Sheet Components

Short-term Investments:

At December 31, 2007, the Company had investments of approximately \$28.6 million in auction rate securities (ARS). The Company generally invests in these securities for short periods of time as part of its cash management program. Subsequent to year end, all short-term investments in ARS have been successfully settled through the dutch auction process in which the Company, along with other investors, had the ability to liquidate positions. Accordingly, the Company's ARS investments, all with contractual maturities greater than one year from year end, were classified as short-term investments at December 31, 2007 and 2006.

Based on an analysis of other-than-temporary impairment factors, the Company determined that the carrying value of the investments in ARS at December 31, 2007 approximated fair value and has, accordingly, recorded no impairment charge at that date. The Company recorded no unrealized gains or losses in conjunction with these investments in 2007 and the amortized costs of such investments are equal to the carrying values as recorded. The Company's valuation included assessments of credit quality, default risk underlying the security, overall capital market liquidity and the subsequent successful auctions for all investments held at December 31, 2007. The valuation of our investment is subject to uncertainties that are difficult to predict and can include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, credit risk and forecasted near-term market recovery.

In early 2008, with the liquidity issues in the global credit and capital markets, the Company was informed that there was insufficient demand at auction for certain of its ARS investments that had reset subsequent to December 31, 2007. As a result, certain of the affected securities are currently not liquid and the interest rates have been reset to predetermined rates per the terms of the investments. The Company has the ability and intent, if necessary, to liquidate certain of its investments to meet the Company's liquidity needs and anticipates, based on discussions with its investment advisors, that liquidity for these securities might be realized through the emergence of secondary markets in the near term. If liquidity is not reestablished in the short term, the Company may be required to reclassify these investments as long-term assets based on the nominal maturity date of the underlying securities. In addition, the value of such investments could potentially be impaired on a temporary or other-than-temporary basis.

Property and equipment:

Property and equipment consist of the following:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Furniture and fixtures	\$ 56,010	\$ 52,818
Software	19,046	19,046
Computer and office equipment	71,047	43,362
	146,103	115,226
Less—accumulated depreciation and amortization	(103,310)	(72,288)
	<u>\$ 42,793</u>	<u>\$ 42,938</u>

Depreciation and amortization expense was \$31,022, \$35,389 and \$25,527 for the years ended December 31, 2007, 2006 and 2005, respectively.

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3. Common Stock Offerings

On November 8, 2007, the Company raised gross proceeds of approximately \$48.9 million through the sale of 7,388,172 shares of its \$0.0001 par value common stock in a registered direct offering. These shares were offered pursuant to the Company's shelf registration statement as filed with the Securities and Exchange Commission under which it may offer shares of its common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of \$60.0 million. Such registration statement became effective as of October 11, 2007. In connection with this offering, the Company paid commissions and recorded or accrued other offering-related expenses of approximately \$3.2 million.

On March 22, 2007, the Company raised gross proceeds of approximately \$12.5 million through the sale of 2,648,306 shares of its \$0.0001 par value common stock plus warrants for the purchase of 794,492 shares of its \$0.0001 par value common stock (the "2007 Placement"). The aggregate fair value of these warrants was approximately \$1.3 million. The warrants permit the holders to purchase the underlying common shares at \$5.66 each and are exercisable in whole at any time, or in part from time to time, for cash, for five years from the date of issuance. The warrants are redeemable at par value at the Company's option in the event that the volume weighted-average closing price of the Company's common stock is greater than \$12.00 per share for any twenty (20) consecutive trading days provided the Company gives sixty (60) business days' written notice to the holders and simultaneously call all warrants on the same terms. Under the terms of the placement, the Company agreed to and filed a registration statement with the SEC within 30 days of the closing for the shares of common stock sold and the shares of common stock underlying the warrants and such registration became effective on August 7, 2007. In connection with this offering, the Company paid commissions and other offering-related expenses of approximately \$1.0 million in cash.

On February 13, 2006, the Company raised gross proceeds of approximately \$21.5 million through the sale of 7,166,666 shares of its \$0.0001 par value common stock plus warrants for the purchase of 2,149,999 shares of its \$0.0001 par value common stock (the "2006 Placement"). The allocated aggregate fair value of these warrants was approximately \$1.1 million. The warrants permit the holders to purchase the underlying common shares, for cash only, at \$4.20 each and are exercisable in whole at any time, or in part from time to time, for five years from the date of issuance. The warrants are redeemable at par value at the Company's option in the event that the Company's volume weighted-average closing bid price of its common stock is greater than \$9.00 per share for any twenty (20) consecutive trading days provided that the Company gives thirty (30) business days' written notice to the holders and simultaneously calls all warrants on the same terms. In connection with this offering, the Company paid commissions and other offering-related expenses of approximately \$1.6 million in cash and issued warrants to the placement agent for the purchase of 716,666 shares of the Company's common stock with an exercise price of \$3.30 per share, or 110% of the price of the shares sold in the offering and an aggregate fair value of approximately \$0.7 million. Under the terms of the 2006 Placement, the Company agreed to and filed a registration statement with the SEC within 30 days of the closing for the shares of common stock sold and the shares of common stock underlying the warrants and such registration became effective on March 29, 2006.

In December 2004, Chelsea Therapeutics, Inc. raised gross proceeds of approximately \$14.5 million through the sale of 5,532,994 shares of its \$0.0001 par value common stock (the "2004 Placement"). The amount raised includes the conversion of a \$1.7 million stockholder loan along with accrued interest, for which a total of 677,919 shares of common stock were issued. In connection with this offering, Chelsea Therapeutics, Inc. paid commissions and other offering-related expenses of approximately \$1.0 million in cash and issued warrants to the placement agent for the purchase of 483,701 shares of its common stock with an aggregate fair value of approximately \$14,000.

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4. Commitments

Facility Lease

In 2004, the Company leased its corporate headquarters under an operating lease, as amended, that expires in June 2008. The lease contains no provisions for renewal periods of any fixed lengths. Rent expense for the years ended December 31, 2007, 2006 and 2005 was \$57,960, \$56,278 and \$54,653, respectively and future minimum payments are \$29,406 for the year ending December 31, 2008.

On March 7, 2008 the Company entered into a lease for office space in Charlotte, North Carolina near our existing office location to serve as its new corporate headquarters. Occupancy is anticipated on or about May 15, 2008 with monthly payments beginning October 15, 2008 of approximately \$19,000. The lease expires on October 15, 2013 and calls for annual rent increases of 3%. In addition, the lease provides an option to rent an additional adjacent space. The option remains in effect until November 2009 at a cost of \$1,750 per month, but may be terminated sooner at the Company's discretion. A security deposit equal to four (4) months rent or approximately \$76,000 was paid upon signing the lease.

License Agreements

In March 2004, the Company entered into a License Agreement with Dr. M. Gopal Nair, Ph.D., of the University of South Alabama College of Medicine, for rights to use, produce, distribute and market products derived from an invention by Dr. Nair, claimed in US Patent # 5,912,251, entitled "metabolically inert anti-inflammatory and antitumor antifolates", designated by Chelsea as CH-1504 and related compounds (the "Antifolate Agreement"). The license provides us exclusive, worldwide (excluding India) rights for CH-1504 and related compounds. The Company made an upfront payment in May 2004 of \$150,000 and anniversary milestone payments as required by the agreement of \$100,000 each in March 2006 and 2005. In April 2007, the Company issued 26,643 shares of its \$0.0001 par value common stock, subject to trading restrictions, at a value of approximately \$5.63 per share, in settlement of the \$150,000 anniversary milestone payment for 2007. The Company is required to make additional payments upon the achievement of specific development and regulatory approval milestones. The Company is also obligated to pay royalties under the agreement until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis. Future potential milestone and anniversary payments total approximately \$1,750,000 at December 31, 2007 and there are no minimum royalties required under the agreement. Subsequent to December 31, 2007, the Company achieved a milestone as defined in the License Agreement related to patient dosing in a Phase II clinical program. In January 2008, the Company recorded a liability of \$100,000 related to achievement of this milestone.

In May 2006, the Company entered into an agreement with Dainippon Sumitomo Pharma Co., Ltd. ("DSP") for a worldwide, exclusive, sub-licensable license and rights to certain intellectual property and proprietary information (the "DSP Agreement") relating to L-threo-3,4-dihydroxyphenylserine ("L-DOPS" or "droxidopa") including, but not limited to all information, formulations, materials, data, drawings, sketches, designs, testing and test results, records and Regulatory Documentation. As consideration for these rights, the Company paid DSP \$100,000 and issued 63,131 shares of its \$0.0001 par value common stock, with a value of approximately \$4.35 per share, or \$274,621. During 2007, the Company made a milestone payment, related to obtaining orphan drug status from the FDA, under the agreement of \$250,000. As additional consideration, the Company agreed to pay DSP and or its designees (1) royalties on the sales should any compound be approved for commercial sale; and (2) milestone payments, payable upon achievement of milestones as defined in the DSP Agreement. At December 31, 2007, remaining potential future milestone payments, subject to the Company's right to terminate

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the license agreement, totaled \$3.75 million. Subsequent to December 31, 2007, the Company began dosing patients in a Phase III clinical program and, as this is a milestone as defined in the DSP Agreement, recorded a liability of \$500,000.

The amount expended under these agreements and charged to research and development expense was \$375,000 during the year ended December 31, 2007; \$474,621, including the value of common stock issued, during the year ended December 31, 2006; and \$100,000 during the year ended December 31, 2005.

Subsequent to execution of the DSP Agreement, the Company and DSP have agreed to initiate, and the Company has agreed to fund, activities focused on modifying the manufacturing capabilities of DSP in order to expand capacity and comply with regulations and requirements of the United States Food and Drug Administration. Such activities are currently ongoing and shall continue over a two-year period. Based on work performed by DSP as of December 31, 2007, the Company had paid approximately \$0.4 million and had accrued an additional \$1.5 million of costs.

Development and Commercialization Agreement

Effective May 2006, the Company entered into a development and commercialization agreement (the "Development Agreement") with Active Biotech AB ("AB") to co-develop and commercialize the I-3D portfolio of orally active, Dihydroorotate dehydrogenase ("DHODH") inhibiting compounds for the treatment of autoimmune diseases and transplant rejection. Under the terms of the license and co-development agreement, an initial payment of \$1.0 million was made to AB at the time of the agreement with such funds utilized to cover the initial costs of research and development efforts jointly approved by both parties. At December 31, 2006 the Company had expensed the entire \$1.0 million payment and expensed additional costs of \$0.3 million. During 2007, the Company expensed costs of \$0.6 million under the program related to costs of research and development including a net accrued expense of approximately \$0.2 million at December 31, 2007. Subsequent clinical development efforts shall be jointly conducted and funded by the Company and AB via a Joint Development Committee with equal representation from both parties. The partnership also establishes a licensing agreement providing Chelsea with the exclusive North and South American commercial rights to all drugs within this portfolio, while Active Biotech will retain rights for the remaining global markets. In addition to sharing development costs, both Chelsea and Active Biotech will pay the other partner royalty payments on sales in their respective markets. Active Biotech will also receive certain defined milestone payments related to clinical development and receipt of revenue from commercialization of the compounds. Unless terminated by either party with six months written notice, the Development Agreement shall remain in effect until the earlier of (1) the expiration of the last to expire patent rights indicated under the Development Agreement or (2) fifteen (15) years from the date of the first commercial sale of the product. As of December 31, 2007, remaining potential future milestone payments, subject to the Company's right to terminate the Development Agreement, totaled \$15.5 million.

Contract Research and Manufacturing Purchase Obligations

The Company often contracts with third parties to facilitate, coordinate and perform agreed upon research and development activities. These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. The Company currently intends to continue its research and manufacturing activities as contracted at December 31, 2007. However, there can be cancellation fees associated with these contracts that could be punitive in nature. Commitments under research and development programs represent contractual commitments entered into for materials and services in the normal course of business and totaled approximately \$16.5 million at December 31, 2007.

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5. Stockholders' Equity

Preferred Stock

The Company's Certificate of Incorporation provides that the Board of Directors of the Company has the authority to issue up to an aggregate of 5,000,000 shares of preferred stock in one or more classes or series and to determine, with respect to any such class or series, the designations, powers, preferences and rights of such class or series, and the qualifications, limitations and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices, liquidation preferences and the number of shares constituting any class or series or the designation of such class or series, without further vote or action by the stockholders.

As of December 31, 2007, no shares of preferred stock were issued and outstanding.

Common Stock

In April 2007, the Company issued 26,643 shares of its \$0.0001 par value common stock, subject to trading restrictions, at a value of approximately \$5.63 per share, as consideration for the \$150,000 anniversary milestone payment due under its product license agreement with DSP (see Note 4).

In May 2006, the Company issued 63,131 shares of its \$0.0001 par value common stock as consideration for a product license agreement with DSP (see Note 4), with a value of approximately \$4.35 per share, or \$274,621.

During April 2004, 471,816 common shares were issued as consideration in the product license agreement (see Note 4) and 478,330 shares were sold to Simon Pedder, the Company's President and Chief Executive Officer under the terms of his employment agreement. These shares were valued at what was, at that time, Chelsea's common stock estimated aggregate fair value of \$402 and \$408, respectively, with such nominal values reflecting an asset-based valuation methodology.

During 2002, the Company issued 5,428,217 shares of its \$0.0001 par value common stock for a subscription receivable of \$4,625.

Warrants

At December 31, 2007 and 2006, the Company had outstanding warrants to purchase 4,292,136 and 3,675,440 shares of the Company's \$0.0001 par value common stock, respectively, at prices ranging from \$2.62 to \$5.66 per share.

In March 2007, in conjunction with 2007 Placement (see Note 3), the Company issued warrants for the purchase of 794,492 shares of its \$0.0001 par value common stock. The aggregate fair value of these warrants was approximately \$1.3 million. The warrants permit the holders to purchase the underlying common shares at \$5.66 each and are exercisable in whole at any time, or in part from time to time, for cash, for five years from the date of issuance. The warrants are redeemable at par value at the Company's option in the event that the volume weighted-average closing price of the Company's common stock is greater than \$12.00 per share for any twenty (20) consecutive trading days provided the Company gives sixty (60) business days' written notice to the holders and simultaneously call all warrants on the same terms.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In May 2006, in conjunction with and as compensation for activities related the product license agreement with DSP (see Note 4) and under a Finder's Agreement, the Company issued warrants to purchase 250,000 shares of its \$0.0001 par value common stock, with an exercise price of \$4.31 per share. The exercise of these warrants was conditioned on an event that did not occur until January 2007. As such, in January 2007 the Company recorded a charge based on the warrants' aggregate fair value at that date of \$433,750.

In February 2006, in conjunction with the 2006 Placement (see Note 3), the Company issued warrants for the purchase of 2,149,999 shares of its \$0.0001 par value common stock. The allocated aggregate fair value of these warrants was approximately \$1.1 million. The warrants permit the holders to purchase the underlying common shares at \$4.20 each and are redeemable at the Company's option in the event that the volume weighted average closing bid price of our common stock for any twenty (20) consecutive trading days is at least \$9.00 per share. The Company also issued warrants to its placement agent to purchase 716,666 shares of its \$0.0001 par value common stock with an exercise price of 110% of the purchase price per share based on shares sold in the 2006 Placement, or \$3.30 per share and an aggregate fair value of approximately \$705,000.

In February 2005, in conjunction with and as compensation for facilitating the Merger (see Note 1), the Company issued warrants for the purchase of 105,516 shares of its \$0.0001 par value common stock at an exercise price of approximately \$2.62 per share. The aggregate fair value of these warrants was approximately \$26,700.

In December 2004, as compensation for fundraising efforts related to the 2004 Placement (see Note 3), the Company issued warrants to purchase 483,701 shares of its \$0.0001 par value common stock, with a purchase price of 110% of the purchase price per share based on shares sold in the 2004 Placement, or, as converted under terms of the Merger Agreement, approximately \$2.89 per share. The aggregate fair value of these warrants was approximately \$14,000.

Exercise of Common Stock Warrants

During 2007, various warrant holders, on various dates, exercised rights to purchase 116,596 shares of the \$0.0001 par value common stock of the Company, with an average exercise price of approximately \$2.90 per share, pursuant to cashless exercises whereby the Company, in net share settlements, issued 68,136 shares of its \$0.0001 par value common stock to the warrant holders based on the excess of the market prices over the exercise prices on the respective dates of exercise.

During 2007, various warrant holders, on various dates, exercised rights to purchase 61,200 shares of the \$0.0001 par value common stock of the Company on a cash basis at an exercise price of \$4.20 per share. The Company recorded cash proceeds, net of expenses, of \$252,040 in conjunction with these transactions.

During 2006, various warrant holders, on various dates, exercised rights to purchase 30,422 shares of the Company's \$0.0001 par value common stock, with an exercise price of approximately \$2.89 per share, pursuant to cashless exercises whereby the Company, in net share settlements, issued 15,461 shares of its \$0.0001 par value common stock to the warrant holders based on the excess of the market prices over the exercise prices on the respective dates of exercise.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock Options

The Company has a stock incentive plan (the "Plan") under which incentive stock options for 4,145,000 shares of the Company's \$0.0001 par value common stock may be granted. Grants under the Plan may be made to employees (including officers), directors, consultants, advisors or other independent contractors who provide services to the Company or its subsidiary.

Options awards to employees and directors are generally granted with an exercise price equal to the market price of the Company's stock at the date of the grant; and generally have 10-year contractual terms.

During the years ended December 31, 2007, 2006 and 2005, the Company granted stock options to employees and non-employee directors for the purchase of 665,500, 668,085 and 756,451 shares of its \$0.0001 par value common stock, respectively. The grants made during the year ended December 31, 2007 had a weighted average exercise price of \$5.72 per share, a weighted average grant date fair value of approximately \$3.39 per share and an aggregate intrinsic value as of December 31, 2007 of approximately \$1.1 million. The grants made during the year ended December 31, 2006 had a weighted average exercise price of \$3.61 per share, a weighted average grant date fair value of approximately \$1.47 per share and an aggregate intrinsic value as of December 31, 2007 of approximately \$2.5 million. The grants made during the year ended December 31, 2005 had a weighted average exercise price of \$2.66 per share, a weighted average grant date fair value of \$0.47 per share and an aggregate intrinsic value as of December 31, 2007 of approximately \$3.5 million. Each option granted to employees and non-employee directors in 2007 and 2006 and to employees in 2005 vests as to 25% of the shares on the first, second, third and fourth anniversary of the vesting commencement date. Each option granted to non-employee directors in 2005 vests as to 100% of the shares on the first anniversary of the vesting commencement date. Following the vesting periods, options are exercisable by employees until the earlier of 90 days after the employee's termination with the Company or the ten-year anniversary of the initial grant, subject to adjustment under certain conditions. Following the vesting periods, options are exercisable by non-employee directors until the earlier of 180 days after they cease to be a member of the Board of Directors or the ten-year anniversary of the initial grant, subject to adjustment under certain conditions (see Note 8).

The Company recorded compensation expense of \$828,626, \$283,983 and \$99,319 for the years ended December 31, 2007, 2006 and 2005, respectively in conjunction with option grants made to employees and non-employee directors. As of December 31, 2007, the Company had total unrecognized compensation expense related to options granted to employees and non-employee directors of approximately \$2.4 million, which will be recognized over a remaining average period of 2.7 years.

In November 2005, the Company granted a stock option to a third-party contractor to purchase 5,000 shares of its \$0.0001 par value common stock at an exercise price of \$3.10 per share. The option vested 25% at each calendar quarter end date from the date of issuance. For the years ended December 31, 2006 and 2005, based on the fair value of these options, the Company recorded compensation expense of \$4,192 and \$5,464, respectively. At December 31, 2007, these options were fully vested.

In December 2004, the Company granted a stock option to a third-party contractor to purchase 58,683 shares of its \$0.0001 par value common stock at an exercise price of \$2.62 per share. The option was scheduled to vest monthly over a 36-month period. On October 31, 2005, the Company terminated its relationship with this contractor and the vested portion of the options subsequently expired unexercised after thirty (30) days. For the year ended December 31, 2005, based on the fair value of these options, the Company recorded compensation expense of \$53,130.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

A summary of the Company's stock option activity and related information since inception is as follows:

	<u>Available For Grant</u>	<u>Activity/ Balance</u>	<u>Wtd Avg Exercise Price</u>
Establish 2002 Option Plan	1,085,648	—	
Balance at December 31, 2002	1,085,648	—	
2003 Activity	—	—	n/a
Balance at December 31, 2003	1,085,648	—	
Cancel 2002 Stock Option Plan	(1,085,648)	—	
Establish 2004 Stock Option Plan	1,085,648	—	
2004 Option grants	(363,835)	363,835	\$0.56
Balance at December 31, 2004	721,813	363,835	
2005 Plan Amendment	410,784	—	
2005 Option grants	(761,451)	761,451	\$2.66
2005 Cancellations	58,683	(58,683)	\$2.62
2005 Exercises	—	(14,663)	\$0.07
Balance at December 31, 2005	429,829	1,051,940	
2006 Plan Amendments	1,148,568	—	
2006 Option grants	(668,085)	668,085	\$3.61
2006 Cancellations	8,802	(8,802)	\$2.62
2006 Exercises	—	(78,683)	\$0.06
Balance at December 31, 2006	919,114	1,632,540	
2007 Plan Amendments	1,500,000	—	
2007 Option grants	(665,500)	665,500	\$5.72
2007 Exercises	—	(17,868)	\$0.88
Balance at December 31, 2007	<u>1,753,614</u>	<u>2,280,172</u>	

As of December 31, 2007, there were 2,280,172 options outstanding under the Plan with a weighted average remaining life of 7.96 years, a weighted average grant date fair value of \$1.58 per share and an intrinsic value of approximately \$8.5 million. Also, options for 748,588 shares had vested and were exercisable at December 31, 2007 with a weighted average remaining contractual life of 7.19 years, a weighted average grant date fair value of \$0.59 per share and an aggregate intrinsic value of approximately \$3.8 million. During the year ended December 31, 2007, options for 17,868 shares were exercised with a weighted average exercise price of \$0.88 per share and an aggregate intrinsic value as of the dates of exercise of approximately \$79,000. During the year ended December 31, 2006, options for 78,683 shares were exercised with a weighted average exercise price of \$0.06 per share and an aggregate intrinsic value as of the dates of exercise of approximately \$0.3 million. During the year ended December 31, 2005, options for 14,663 shares were exercised with a weighted average exercise price of \$0.07 per share and an aggregate intrinsic value as of the date of exercise of approximately \$43,000. The weighted average exercise price for all vested and unvested options outstanding as of December 31, 2007, 2006 and 2005 is approximately \$3.62, \$2.73 and \$1.98 per share, respectively.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	December 31,		
	2007	2006	2005
Common stock warrants outstanding	4,292,136	3,675,440	589,217
Common stock options outstanding	2,280,172	1,632,540	1,051,940
Common stock options available for future grants	1,753,614	919,114	429,829
	<u>8,325,922</u>	<u>6,227,094</u>	<u>2,070,986</u>

6. Income Taxes

The Company believes that there are no uncertain tax positions that fail to meet the more likely than not recognition threshold under FIN 48 to be sustained upon examination. As such, a tabular presentation of those tax benefits taken that do not qualify for recognition is not presented.

From time to time, the Company may be assessed interest or penalties by its tax jurisdictions, although, historically, there have been no such assessments and the Company believes that any potential future assessments would be minimal and immaterial to the Company's results of operations and financial position. In the event the Company receives an assessment for interest and/or penalties, it would be classified in the consolidated financial statements as general and administrative expense.

The Company and its subsidiaries file tax returns in the United States and a small number of state jurisdictions. The statute of limitations for examination of the Company's returns has expired for years prior to 2004. There are no income tax examinations currently in process nor has the Company been subject to examination since inception. The material jurisdictions subject to potential examination by taxing authorities for open tax years primarily include the United States and North Carolina.

The components of the deferred tax assets and the valuation allowance are shown below. The state carryforwards are shown net of federal tax.

	December 31,		
	2007	2006	2005
Deferred tax assets:			
Net operating loss carryforward—Federal	\$ 10,997,542	\$ 6,239,258	\$ 3,554,624
Net operating loss carryforward—State	1,487,903	844,135	480,920
Licensing costs	434,334	289,584	96,655
Compensation costs and deferred stock compensation	459,850	162,531	46,419
Other temporary differences	(27,694)	7,344	26,919
	<u>13,351,935</u>	<u>7,542,852</u>	<u>4,205,537</u>
Less valuation allowance	<u>(13,351,935)</u>	<u>(7,542,852)</u>	<u>(4,205,537)</u>
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The reasons for the difference between actual income tax benefit and the amount computed by applying the statutory federal income tax rate to the losses before income tax benefit are as follows:

	December 31,		
	2007	2006	2005
Rate reconciliation:			
Statutory federal rate	-34.00%	-34.00%	-34.00%
State income tax rate (net of federal benefit)	-4.60%	-4.60%	-4.60%
Certain non-deductible expenses	0.08%	0.11%	0.13%
Effect of increase in valuation allowance	38.52%	38.49%	38.47%
Effective tax rate	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

Given the Company's history of incurring operating losses, the Company's ability to realize its deferred tax assets is not considered more likely than not. As a result, a valuation allowance equal to the total deferred tax assets has been established. The valuation allowance as of December 31, 2007, 2006 and 2005 was approximately \$13.4 million, \$7.5 million and \$4.2 million, respectively.

At December 31, 2007, the Company had potentially utilizable federal and state net operating loss carryforwards of approximately \$32.3 million. The net operating loss carryforwards expire in various amounts for federal and state tax purposes through 2027 and 2022, respectively.

The utilization of the Company's net operating losses may be subject to a substantial limitation should a change of ownership occur or have occurred, as defined under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation could result in the expiration of the net operating loss carryforwards before their utilization. In 2008, the Company plans to undertake a detailed study to estimate the potential impact of any §382 limitations on the utilization of its net operating losses as well as the potential impact of any §383 limitations on the utilization of research and development tax credits that may be available to the Company. Based on a preliminary evaluation, the Company does not believe that the impact of such limitations will be material but until such studies are completed, the Company is unable to fully estimate the impact of any such limitations.

7. Savings and Retirement Plan

During 2005, the Company established a savings and retirement plan under Section 401(k) of the Internal Revenue Code that allows eligible employees to annually contribute a portion of their annual salary to the plan. The Company matches such contributions up to a maximum of 4% of the employee's compensation, as defined. For the years ended December 31, 2007, 2006 and 2005, the Company made contributions of \$85,333, \$47,695 and \$38,894, respectively.

8. Subsequent Events

Licensing Milestone Payments

In January 2008, the Company initiated patient dosing in a Phase II clinical program for CH-1504 in the treatment of rheumatoid arthritis. Based on the terms of the CH-1504 Agreement (see Note 4), the initiation of patient dosing generated a liability of \$100,000. The Company recorded such liability in January 2008.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In February 2008, the Company initiated patient dosing in a Phase III clinical program for droxidopa in the treatment of neurogenic orthostatic hypotension. Based on the terms of the DSP Agreement (see Note 4), the initiation of patient dosing generated a liability of \$500,000. The Company recorded such liability in February 2008.

Grant of Stock Options

In January 2008 the Company granted options for the purchase of 625,000 shares of its \$0.0001 par value common stock to employees and non-employee directors. These grants, made during the first quarter of 2008, have a weighted average exercise price of \$6.46 per share, a weighted average fair value of \$3.59 per share and were granted at an exercise price equal to the closing market value of the Company's stock on the dates of grant.

Modification of Previously Awarded Stock Options

In January 2008 the Board of Directors approved a modification for all grants previously made to non-employee directors, extending the exercise term upon termination with the Company from 90 days to 180 days. In addition, the grants previously made to Dr. Jason Stein, a non-employee director, were modified to extend the exercise term upon termination with the Company from 90 days, or May 8, 2008 based upon Dr. Stein's resignation date from the Board of Directors, until December 31, 2008. As a result of these modifications, the Company's total unrecognized compensation expense related to options granted increased by approximately \$10,000.

Chelsea Information

Directors:

- Kevan Clemens, PhD – Chairman
- Simon Pedder, PhD
- Norman Hardman, PhD
- Johnson Y.N. Lau, MB, BS, MD, FRCP
- Roger Stoll, PhD
- Michael Weiser, MD, PhD

Officers:

- Simon Pedder, PhD – President and Chief Executive Officer
- L. Arthur Hewitt, PhD – Vice President, Drug Development
- J. Nick Riehle, MBA – Vice President, Administration & Chief Financial Officer
- Keith Schmidt, MBA – Vice President, Sales and Market

Headquarters:

13950 Ballantyne Corporate Place
Suite 325
Charlotte, NC 28277
Phone: (704) 341-1516
Fax: (704) 752-1479

Effective June 1, 2008, our address will be:

3530 Toringdon Way
Suite 200
Charlotte, NC 28277
Phone: (704) 341-1516
Fax: (704) 752-1479

Transfer Agent and Registrar:

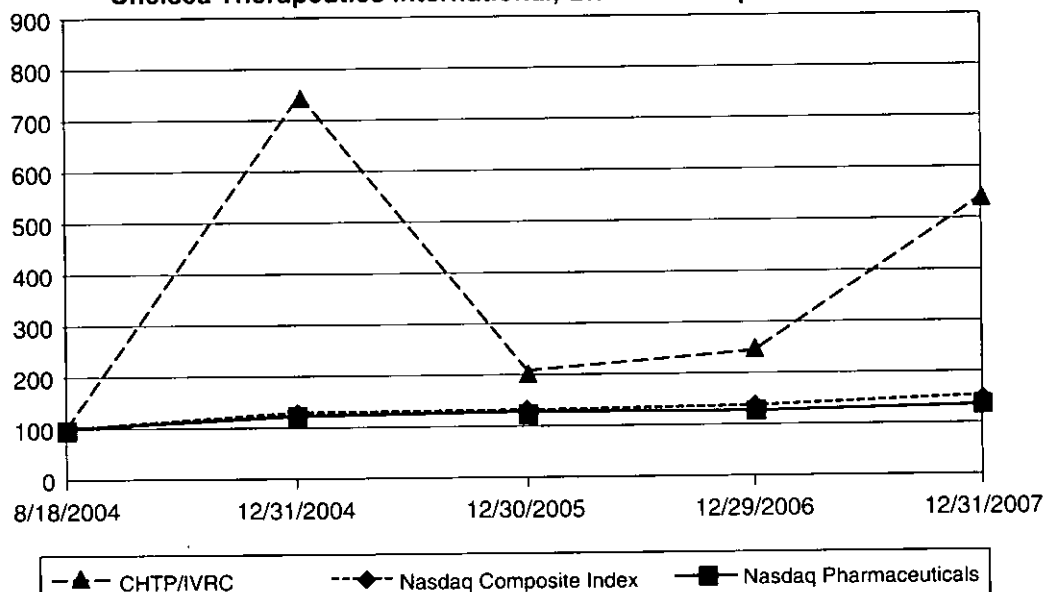
Corporate Stock Transfer, Inc.
3200 Cherry Creek South Drive, Suite 430
Denver, Colorado 80209
Phone: (303) 282-4800

Website: www.chelseatherapeutics.com

Stock Listing: Chelsea Therapeutics International, Ltd. common stock is listed on the Nasdaq Capital Market and quoted under the symbol CHTP

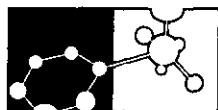
Performance Graph

**Comparison of the Cumulative Total Return Among
Chelsea Therapeutics International, Ltd. and Comparative Indices**



This graph compares our cumulative total stockholder return from August 18, 2004 with those of the Nasdaq Composite Index and the Nasdaq Pharmaceuticals Index. The graph assumes that U.S. \$100 was invested on August 18, 2004 in (1) our common stock, (2) the Nasdaq Composite Index, (3) the Nasdaq Pharmaceuticals Index, and that all dividends were reinvested. Note that historic stock price performance is not necessarily indicative of future stock price performance.

END



CHELSEA
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